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

IN RE: BABY FOOD PRODUCTS
LIABILITY LITIGATION

Case No. 24-MD-3101-JSC

MDL 3101

This document relates to:

Hon. Jacqueline Scott Corley

ALL ACTIONS

MASTER LONG-FORM COMPLAINT

DEMAND FOR JURY

Plaintiffs in those cases consolidated and filed into this Multi-District Litigation (“MDL”) submit this Master Long-Form Complaint (“Complaint”) against the below-named Defendants. Plaintiffs seek equitable relief, monetary restitution, and/or compensatory and punitive damages. Plaintiffs make the following allegations based upon personal knowledge and information and belief, as well as the investigation carried out by Plaintiffs’ Lead Counsel, Plaintiffs’ Steering Committee, and Plaintiffs’ Liaison Counsel.

This Complaint does not constitute a waiver or dismissal of any claims asserted in individual actions, and Plaintiffs reserve the right to amend this Complaint based upon newly discovered facts and/or evidence.

The purpose of this Complaint is to provide general allegations as they apply to each Defendant, which can then be adopted in part or in whole by individual Plaintiffs filing Short-Form Complaints. This Complaint in addition to a filed Short Form Complaint, constitute each Plaintiffs’ pleading under Fed. R. Civ. P. 3.

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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 that
4 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 detectable
6 amounts of Toxic Heavy Metals (collectively “Contaminated Baby Food”) those products were
7 defective in their manufacture, design, and labeling. Babies are the most vulnerable segment of the
8 population, and they rely on that food for healthy neurodevelopment. Defendants justify this callous
9 disregard for the welfare of babies because, until recently, there were no regulations governing the
10 presence of Toxic Heavy Metals in baby foods—and, because there were no regulations, they were
11 free to do as they pleased.

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

24 3. Plaintiffs, here, are all children that live with brain injuries and neurodevelopmental
25 harm caused by exposure to the Defendants’ Contaminated Baby Food, which has manifested in
26 diagnoses of autism spectrum disorder (“ASD”) and/or attention deficit hyperactivity disorder
27 (“ADHD”). Their parents/guardians/caregivers were never warned that the Defendants’ food
28 contained Toxic Heavy Metals and, thus, were never able to make an informed decision about

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

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

8 **PARTIES**

9 **I. Plaintiffs**

10 5. Plaintiffs, each, are children who live with brain injuries and neurodevelopmental
11 harm caused by exposure to the Defendants' Contaminated Baby Food, which has manifested in a
12 diagnosis of ASD and/or ADHD.

13 6. Plaintiffs allege that as a direct and proximate result of each Plaintiff's exposure to
14 Toxic Heavy Metals from consumption of Defendants' Contaminated Baby Foods, they suffered
15 significant harm, conscious pain and suffering, physical injury and bodily impairment including, but
16 not limited to, brain injury manifesting as the neurodevelopmental disorders ASD and/or ADHD,
17 other permanent physical deficits, permanent bodily impairment, and other *sequelae*. Plaintiffs'
18 injuries required medical intervention to address the adverse neurological effects and damage caused
19 by exposure to Toxic Heavy Metals in Defendants' Contaminated Baby Foods. Additionally, each
20 Plaintiff has suffered severe mental and physical pain, including but not limited to, pain, mental
21 suffering, loss of enjoyment of life, disfigurement, physical impairment, inconvenience, grief,
22 anxiety, humiliation, and emotional distress and have and will sustain such injuries, along with
23 economic loss due to medical expenses and living-related expenses as a result of lifestyle changes,
24 into the future, as determined by the Trier of Fact.

25 7. The product warnings for the Contaminated Baby Foods in effect during the time
26 period Plaintiffs consumed the Contaminated Baby Foods were non-existent, vague, incomplete
27 and/or otherwise inadequate, both substantively and graphically, to alert consumers to the presence of
28 Toxic Heavy Metals in the Contaminated Baby Foods and/or the potentially severe health risks

1 associated with Toxic Heavy Metal exposure in babies. Thus, each Defendant did not provide
2 adequate warnings to consumers including Plaintiffs, their parents, guardians and/or caregivers, and
3 the general public about the presence of Toxic Heavy Metals in the Contaminated Baby Foods
4 consumed by Plaintiffs and the potential risk of the serious adverse events associated with Toxic
5 Heavy Metal exposure in infancy.

6 8. Had Plaintiffs or their parents/guardians/caregivers been adequately warned by the
7 Defendants of the potential for exposure to Toxic Heavy Metals from consumption of Defendants'
8 Baby Foods, and/or the potential for such exposure to result in harm, Plaintiffs, or their
9 parents/guardians/caregivers would not have purchased, used and/or consumed Contaminated Baby
10 Foods or would have taken other steps to potentially mitigate the harm caused by exposing a baby to
11 Toxic Heavy Metals.

12 **II. Defendants**

13 9. The following are the Defendants listed in this Complaint. These Defendants can be
14 named or not named by individual Plaintiffs in their Short Form Complaint, and the omission of a
15 Defendant here does not preclude the addition of other Defendants within a Short Form Complaint.

16 In alphabetical order:

- 17 1. Beech-Nut Nutrition Company (“Beech-Nut”)
- 18 2. Campbell Soup Company (“Campbell”)
- 19 3. Danone S.A. (“Danone”)
- 20 4. Gerber Products Company (“Gerber”)
- 21 5. Hain Celestial Group, Inc. (“Hain”)
- 22 6. Hero A.G. (“Hero Group”)
- 23 7. Neptune Wellness Solutions (“Neptune”)
- 24 8. Nestlé Holdings, Inc. (“NHI”)
- 25 9. Nestlé S.A. (“Nestlé”)
- 26 10. Nurture, LLC (“Nurture”)
- 27 11. Plum, PBC (“Plum”)
- 28 12. Sprout Foods, Inc. (“Sprout”)

1 13. Sun-Maid Growers of California (“Sun-Maid”)

2 14. Walmart, Inc. (“Walmart”)

3 **A. Beech-Nut**

4 10. Defendant Beech-Nut Nutrition Company (“Beech-Nut”) is a citizen of Delaware and
5 New York with its principal place of business located at 1 Nutritious Pl., Amsterdam, New York
6 12010. Beech-Nut is wholly owned, controlled, and operated by the Hero Group, which considers
7 Beech-Nut to be one of its brands. In the Hero Group’s 2023 annual report, it states “Hero markets
8 baby food in the US and Canada under the brand names Beech[-]Nut and Baby Gourmet.” Beech-
9 Nut branded baby foods aim at infants 4+ months up to 12+ months and include a variety of cereals,
10 “jars,” and “pouches” for these age groups. At all relevant times, Beech-Nut has conducted business
11 and derived substantial revenue from its manufacturing, advertising, distributing, selling, and
12 marketing of Baby Foods within this judicial district and throughout the United States.

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

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

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

1 **B. Gerber**

2 14. Defendant Gerber Products Company (“Gerber”) is a citizen of Michigan and Virginia
3 with its principal place of business located at 1812 N. Moore Street, Arlington, Virginia 22209.
4 Gerber sells Baby Foods under the brand name Gerber. Gerber organizes its products into broad
5 categories of “formula,” “baby cereal,” “baby food,” “snacks,” “meals & sides,” “beverages,” and
6 “organic.” At all relevant times, Gerber has conducted business and derived substantial revenue from
7 its manufacturing, labeling, advertising, distributing, selling, and marketing of baby foods. Gerber is
8 a wholly owned subsidiary of and is directly controlled by Nestlé Holdings, Inc.

9 15. Defendant Nestlé Holdings, Inc. (“NHI”) is a citizen of Delaware and Virginia with its
10 principal place of business located at 1812 N. Moore Street, Arlington, Virginia 22209. According to
11 its December 2023 annual report, “NHI is the holding company for Nestlé S.A.’s principal operating
12 subsidiaries in the United States, which include, among others, Nestlé USA, Inc., Nestlé Purina
13 Petcare Company, and Gerber Products Company.” NHI is a wholly owned subsidiary of Nestlé S.A.
14 (“Nestlé”). Thus, NHI is the holding company for Nestlé that directly controls and operates Gerber—
15 as noted by the sharing of the same address. Indeed, nearly every safety specialist that oversees the
16 heavy metal content of Gerber baby foods, working currently in the internal project “Metallica,” are
17 employed directly by NHI and/or Nestlé S.A. At all relevant times, NHI conducted business and
18 derived substantial revenue through Gerber by manufacturing, advertising, distributing, selling, and
19 marketing baby foods within the judicial districts involved in this litigation.

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

1 advertising, distributing, selling, and marketing baby foods within the judicial districts involved in
2 this litigation.

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

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

10 **C. Hain**

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

18 **D. Nurture**

19 20. Defendant Nurture, LLC (“Nurture”) is a citizen of Delaware and New York with its
20 principal place of business located at 40 Fulton St., 17th Floor, New York, New York 10038-1850.
21 Upon information and belief, Danone S.A. is the only member of Nurture. Prior to 2022, Nurture
22 was incorporated under Delaware law as Nurture, Inc., of which 100% of all Nurture stock was
23 owned by Danone S.A. Nurture does business as (i.e., dba) “Happy Family Organics” and sells baby
24 foods under the brands Happy Baby, Happy Tot, and Happy Family. Nurture classifies its Happy
25 Baby range of products according to three categories: “baby,” “tot,” and “mama.” The “baby”
26 category is comprised of foods, including “starting solids,” intended for age groups 0-7+ months, the
27 “tot” category covers 12+ months, and “mama” includes infant formulas for newborn babies. At all
28 relevant times, Nurture has conducted business and derived substantial revenue from its

1 manufacturing, advertising, distributing, selling, and marketing of baby foods within this judicial
2 district and throughout the United States.

3 21. Defendant Danone S.A. (“Danone”) is a citizen of France, with its principal place of
4 business located at 17 Boulevard Haussmann, 75009 Paris, France. Danone is a global food and
5 beverage company built on four businesses: Essential Dairy and Plant-Based Products, Waters, Early
6 Life Nutrition, and Medical Nutrition. Danone sells products in over 120 markets. As of 2023,
7 Danone generated sales of 27.6 billion euros, with 6.9 billion in sales in North America and 8.5
8 billion in sales attributable to Specialized Nutrition, which includes Early Life Nutrition. Danone
9 sells baby food through its subsidiary, Nurture. Indeed, many of the scientists and researchers that
10 monitored the safety of Toxic Heavy Metals in baby food were directly employed by Danone or were
11 directly controlled and trained by Danone agents and employees. Danone set standards, made
12 executive-level business decisions, and exercised control over Nurture’s baby food selling in the
13 United States. Danone, thus, has been directly involved in the tortious conduct in the United States
14 and its various states that gives rise to these lawsuits. At all relevant times, Danone conducted
15 business and derived substantial revenue through Nurture by manufacturing, advertising, distributing,
16 selling, and marketing baby foods within the judicial districts involved in this litigation.

17 22. Nurture was founded in 2003 by Shazi Visram, started selling baby food products in
18 2006, and was acquired by Danone S.A. in May 2013.

19 23. For the purposes of this Complaint, allegations related to Nurture or Happy
20 Family/Happy Baby apply equally to Danone, as each Defendant exercised authority and control over
21 the sale, manufacture, and distribution of Nurture’s Contaminated Baby Foods at issue in this MDL.

22 **E. Plum**

23 24. Defendant Plum, PBC (“Plum”) is a citizen of Delaware and California with its
24 principal place of business located at 6795 N. Palm Ave., 2nd Floor, Fresno, California 93704. Plum
25 sells Baby Foods under the brand name “Plum Organics” and has done so since 2007. Starting in
26 2013, and until May 3, 2021, Plum was directly controlled and owned by Defendant Campbell.
27 Plum’s products are divided into groups according to the targeted infant or toddler age and/or type of
28 food product. For example, there are five groups designated for the youngest infants: Stage 1 (4+

1 months old), Stage 2 (6+ months old), Stage 3 (6+ months old), “Super Puffs,” and “Little Teethers.”
2 At all relevant times, Plum has conducted business and derived substantial revenue from its
3 manufacturing, advertising, distributing, selling, and marketing of baby foods within this judicial
4 district and throughout the United States.

5 25. Defendant Campbell Soup Company (“Campbell”) is a Citizen of New Jersey with its
6 principal place of business located at One Campbell Pl., Camden, New Jersey 08103. Campbell sells
7 food and beverages and was the parent company of Plum until May 3, 2021, wherein Campbell sold
8 Plum to Defendant Sun-Maid, a few months after the first heavy metal lawsuits were filed. Campbell
9 sold baby food under the brand name Plum Organics through Plum. Indeed, many of the scientists
10 and researchers that monitored the safety of Toxic Heavy Metals in Plum’s baby foods were directly
11 employed by Campbell or were directly controlled and trained by Campbell agents and employees.
12 For example, it was Campbell’s attorneys that responded to Congressional inquiries about heavy
13 metals in Plum baby foods in 2019. Campbell exercised control over Plum’s baby food selling in the
14 United States until May 3, 2021. At all relevant times, Campbell conducted business and derived
15 substantial revenues from its manufacturing, advertising, distributing, selling, and marketing of baby
16 foods within this judicial district and throughout the United States.

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

28 27. For the purposes of this Complaint, allegations related to Plum between 2013 and May

1 3, 2021 apply equally to Campbell, unless otherwise specified, and allegations related to Plum after
2 May 3, 2021 apply equally to Sun-Maid, as each Defendant exercised authority and control over the
3 sale, manufacture, and distribution of Plum’s Contaminated Baby Foods at issue in this MDL.

4 **F. Sprout**

5 28. Defendant Sprout Foods, Inc. (“Sprout”) is a citizen of Delaware and New Jersey with
6 its principal place of business located at 50 Chestnut Ridge Rd, Montvale, New Jersey 07645. Sprout
7 sells Baby Foods under the brand name Sprout Organic Foods. Sprout organizes its Baby Foods
8 selection according to three categories: Stage 2 (6 months+); Stage 3 (8 months+); and Toddler.
9 Sprout was founded in 2008 and was sold to Defendant Neptune Wellness Solutions in February
10 2021. Since Neptune acquired Sprout, it has exercised managerial control over the company, and
11 thus has exercised direct control over the sale of Sprout baby food since that time. At all relevant
12 times, Sprout has conducted business and derived substantial revenue from its manufacturing,
13 advertising, distributing, selling, and marketing of Baby Foods within the United States.

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

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

1 was centralized here under 28 U.S.C. § 1407.

2 37. Venue is proper in this District under 28 U.S.C. § 1391(a) for cases filed here because
3 a substantial part of the events and omissions giving rise to those Plaintiffs' claims occurred in this
4 district.

5 38. Danone, 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 continuous
8 contacts in these judicial districts, regularly transact business within these districts, and regularly
9 avail themselves of the benefits of these districts. These Defendants caused tortious injury by acts
10 and omissions in these judicial districts and by acts and omissions outside these districts while
11 regularly doing and soliciting business, engaging in a persistent course of conduct, and deriving
12 substantial revenue from goods used or consumed and services rendered in these districts.

13 **FACTUAL ALLEGATIONS**

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

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

26 40. The results of the HBBF report were consistent with that of the U.S. Food and Drug
27 Administration (“FDA”) which had, in 2017, detected one or more of the four Toxic Heavy Metals in
28 33 of 39 types of baby food tested. However, the HBBF reported that “[f]or 88 percent of baby foods

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

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

14 **II. Congressional Investigation Finds Substantial Presence of Heavy Metals in Baby Foods** 15 **Manufactured and/or Sold by Defendants, Sparking National Outrage**

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

25 43. Congress reported that the data submitted by the companies unequivocally revealed
26 that a substantial number of Defendants’ finished products and/or ingredients used to manufacture the
27 Baby Foods are tainted with Toxic Heavy Metals, namely lead, arsenic, mercury, and cadmium.
28 And, where the Defendants did set internal limits for the amount of metals they allowed in their

1 foods, Defendants routinely flouted their own limits and sold foods that consistently tested above
2 their limits. Congress found the following:

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

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

25 46. **Hain (Earth’s Best Organic).** Hain sold finished baby food products containing as
26 much as 129 ppb inorganic arsenic. Hain typically only tested its ingredients, not finished products.
27 Documents show that Hain used ingredients testing as high as 309 ppb arsenic. Hain used ingredients
28 containing as much as 352 ppb lead. Hain used many ingredients with high lead content, including

1 88 that tested over 20 ppb lead and six that tested over 200 ppb lead. And, Hain does not even test
2 for mercury in its baby food. However, independent testing by HBBF of Hain’s Baby Foods confirm
3 that Hain’s products contain as much as 2.4 ppb of mercury.

4 47. **Nurture (HappyBABY).** Nurture and its parent company, Danone, sold baby foods
5 after tests showed they contained as much as 180 ppb inorganic arsenic. Over 25% of the products
6 Danone and Nurture tested before sale contained over 100 ppb inorganic arsenic. Danone and
7 Nurture’s testing shows that the typical baby food product it sold contained 60 ppb inorganic arsenic.
8 Danone and Nurture sold finished baby food products that tested as high as 641 ppb lead. Almost
9 20% of the finished baby food products that Danone and Nurture tested contained over 10 ppb lead.
10 Moreover, Danone and Nurture sold finished baby food products containing as much as 10 ppb
11 mercury.

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

1 internal acknowledgement of their high metal content, follows that of the other Defendants discussed
2 in this Complaint, and discovery here will further flesh out the extent of Campbell and Plum’s
3 culpable conduct.

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

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

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

28 52. Following the publication of the Subcommittee Report, Walmart provided documents

1 to the Subcommittee. On September 29, 2021, the House Subcommittee released a subsequent report
2 entitled “New Disclosures Show Dangerous Levels of Toxic Heavy Metals in Even More Baby
3 Foods.” The Subcommittee report addendum described the documents from Walmart as “revealing a
4 concerning lack of attention to toxic heavy metal levels in baby food and an abandonment of its
5 previously more protective standards.” Walmart does not appear to conduct any testing of its baby
6 food products. Walmart sets maximum arsenic and lead levels and asks the manufacturer of its
7 private label to self-certify, but Walmart does not appear to collect any test data or check the
8 accuracy of those certifications. Walmart does not require any mercury or cadmium testing and does
9 not set any standards for mercury or cadmium levels.

10 53. The metal concentrations discussed above and further below surpass the limits allowed
11 by U.S. regulatory agencies. There are no FDA final regulations governing the presence of Toxic
12 Heavy Metals in the majority of Baby Foods with the exception of 100 ppb inorganic arsenic in infant
13 rice cereal and proposed (not yet final) limits for lead in certain baby food categories. To the extent
14 such regulations exist, the quantities of Toxic Heavy Metals in Defendants’ Baby Foods exceed any
15 permissible FDA levels. To be sure, the FDA has set the maximum contaminant levels (“MCL”) in
16 bottled water at 10 ppb inorganic arsenic, 5 ppb lead, and the EPA has capped the allowable level of
17 mercury in drinking water at 2 ppb. However, these limits were created in reference to *adult*
18 exposure, not infants. Compared to these thresholds, the test results of the Defendants’ baby foods
19 and their ingredients are multiple folds greater than the permitted metal levels. Moreover,
20 compounding these troubling findings, the Defendants set internal limits for the presence of Toxic
21 Heavy Metals in their foods that were, themselves, dangerously high and then routinely failed to
22 abide by those inadequate standards, as discussed below.

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

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

28 55. Several factors drive the Toxic Heavy Metal contamination of Defendants’ baby

1 foods, all of which are within Defendants’ control.

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

10 57. *Second*, some Defendants implemented dangerously high internal limits
11 (“specifications” or “specs”) for the maximum level of Toxic Heavy Metals that Defendants allowed
12 in the baby foods. Such high limits—untethered to any consideration of the low levels at which
13 metals are capable of damaging babies’ brains—allowed Defendants to source and use ingredients
14 that contained elevated Toxic Heavy Metals to manufacture the baby foods consumed by Plaintiffs.
15 In the highly competitive and lucrative baby food market, using contaminated ingredients allows each
16 Defendant to retain greater market share.

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

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

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

5 61. **Beech-Nut.** Beech-Nut and Hero Group did not test their finished baby foods for
6 heavy metals, only ingredients. And, Beech-Nut and Hero Group regularly accepted ingredients
7 testing far higher than its internal limits for Toxic Heavy Metals. They justified such deviations as
8 “exceptional releases.” For example, Beech-Nut and Hero Group “exceptionally released” 160,000
9 pounds of sweet potatoes for their baby food products notwithstanding the ingredient testing twice as
10 high as Beech-Nut’s internal heavy metal limit for lead.

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

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

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

28 65. **Gerber.** Gerber, NHI, and Nestlé tested ingredients and, occasionally, finished

1 products. However, while Gerber, NHI, and Nestlé were the only Defendants to test both ingredients
2 and finished products with any regularity, they set high heavy metal limits that rendered their food
3 unsafe. For baby foods generally, between 2012 and 2019, Gerber, NHI, and Nestlé set a limit of 40
4 ppb for lead, 20 ppb for arsenic, and 10 ppb for mercury. For infant rice cereal, between 2012 and
5 2017, Gerber, NHI, and Nestlé set a lead limit of 100 ppb, with a “target” of 50 ppb in 2016 and
6 2017. Between 2018 and 2019, Gerber, NHI, and Nestlé set a lead limit for 50 ppb. For arsenic in
7 rice cereal, between 2012 and 2015, Gerber, NHI, and Nestlé did not have a limit, merely a target of
8 100 ppb. Then, between 2016 and 2018, it set the arsenic limit at 100 ppb. By 2019, Gerber, NHI,
9 and Nestlé increased the arsenic limit to 130 ppb for cereals with 90% rice (and kept the limit at 100
10 ppb for other cereals). For snack foods, Gerber, NHI, and Nestlé had a lead limit of 150 ppb between
11 2012 and 2014. It was reduced to 100 ppb in 2016 and 2017, and then went down to 50 ppb in 2018
12 and 2019. There was no limit for arsenic in snack food prior 2016, just a “target” of 100 ppb. Then a
13 100-ppb arsenic limit was set starting in 2016. For both infant cereal and snacks, Gerber, NHI, and
14 Nestlé imposed a 30-ppb limit for mercury in infant cereal between 2012 and 2016, and reduced it to
15 10 ppb from 2017 onward. With these exceptionally high limits, Gerber, NHI, and Nestlé sold baby
16 foods that were dangerous for infant consumption. They did this knowingly.

17 66. Gerber, NHI, and Nestlé would also audit and re-test Toxic Heavy Metal results
18 submitted by suppliers, and find that the certification from suppliers were incorrect or false. Gerber,
19 NHI, and Nestlé would nonetheless use the certified results and release products despite the
20 ingredients not meeting specifications or being safe for infant consumption.

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

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

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

13 70. Moreover, compounding these troubling findings, Gerber, NHI, and Nestlé historically
14 only tested certain ingredients of its baby food products and only occasionally tested the finished
15 products consumed by babies. It was not until recently that Gerber, NHI, and Nestlé started to
16 implement finished product testing on a more regular basis.

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

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

1 could not explain it.

2 73. Hain would routinely accept ingredients that tested above specifications and use them
3 in baby foods anyway. These “exceptional” releases were made because there were no FDA
4 regulations specifically preventing them.

5 74. Because Hain only tested ingredients, and not finished products, they would
6 underestimate metal exposure. For example, in August 2019, the FDA did what Hain had refused: it
7 actually tested Hain’s baby food products for heavy metals. FDA sampled Hain’s rice cereal and
8 found levels in excess of 100 ppb. FDA tested 20 of Hain’s rice cereal products (all manufactured by
9 Beech-Nut for Hain) sold between September 2017 and June 2018, and found 9 samples in excess of
10 100 ppb of inorganic arsenic, and 16 (80%) above 90 ppb. The FDA raised concern about Hain’s
11 failure to test finished product, and asked Hain to conduct an investigation. These concerns about
12 Hain’s rice cereal were independently confirmed by HBBF, where they found 113 and 107 ppb of
13 inorganic arsenic (138 and 126 ppb of arsenic) in those same products. As a result of the FDA-
14 ordered investigation, Hain learned that its rice cereal exceeded FDA arsenic levels because Hain
15 never accounted for the arsenic added to the product from the vitamin premix. Hain discovered that
16 the vitamin premix specification was 3,000 ppb for arsenic and 4,000 ppb for lead. They realized that
17 their products needed to be tested in finished form to actually estimate the levels of heavy metals in
18 their foods. Hain also realized that the use of brown rice was contributing to the high levels of
19 arsenic, so, thereafter, they started using white rice (as opposed to brown rice) to reduce arsenic
20 levels and began testing rice cereal regularly.

21 75. Hain’s inept process of monitoring the safety of their baby foods resulted in products
22 being sold that contained Toxic Heavy Metals, and this was done with full knowledge of the risks.
23 When asked why Hain did not warn consumers of the Toxic Heavy Metals in their foods, Hain
24 responded that if they warned, people would not buy their products.

25 76. **Nurture.** Since 2006, Defendant Nurture, under the name Happy Family Organics,
26 has sold a wide variety of baby food products. It was not until 2013—seven years after sales began—
27 and after the Danone acquisition, that Nurture and Danone started testing its finished baby food
28 products for lead. This testing, however, remained infrequent and occurred only after the products

1 had been released to the public—not as a condition of product release. Indeed, as of July of 2021,
2 Nurture was still not testing every batch or lot of its baby food products for heavy metals and was not
3 including heavy metal testing as a condition of release.

4 77. Nurture and Danone took a lackadaisical approach to sourcing oversight. For
5 example, Nurture and Danone partnered with co-manufacturer companies to make many of their baby
6 food products, a common practice within the industry. However, Nurture and Danone did not always
7 require those co-manufacturers to provide information regarding the farms where ingredients were
8 grown. Although Nurture and Danone advertise to consumers that they have “Farmer Partners” who
9 they “trust to grow our ingredients,” Nurture and Danone did not even participate in selecting the
10 farms from which co-manufacturers sourced their ingredients. As a result, Nurture and Danone do
11 not even know all of the individual farms that grow their food, making it impossible to ensure that all
12 of their ingredients were sourced from approved farms. To make matters worse, they chose not to
13 require all of their suppliers to have specifications addressing limits for heavy metals in acceptable
14 products. This practice all but ensured that Nurture and Danone would never have a fully accurate
15 picture of the levels of heavy metals in their ingredients or whether there were particular farms or
16 regions that should be avoided.

17 78. And yet, all the while, Nurture and Danone knew that toxic heavy metals in their baby
18 food could cause brain damage in children. Not only did Nurture and Danone know of the dangers
19 heavy metals in their food posed to children, they also trained their employees on that specific risk.
20 For example, Nurture and Danone knew that dangerous levels of arsenic existed in the rice that
21 served as the base for many of its baby food products. Despite this knowledge, Nurture never
22 removed rice from its products.

23 79. But in full view of this knowledge and with full understanding of their lackadaisical
24 ingredient oversight approach, Nurture and Danone chose to rarely test their finished products for
25 toxic heavy metals. And when they did test their products, they sold them regardless of what the tests
26 showed. For example, Danone and Nurture sold baby foods after tests showed they contained as
27 much as 180 ppb inorganic arsenic. Over 25% of the products Nurture tested before sale contained
28 over 100 ppb inorganic arsenic. Nurture’s testing shows that the typical baby food product it sold

1 contained 60 ppb inorganic arsenic. Danone and Nurture sold finished baby food products that tested
2 as high as 641 ppb lead. Almost 20% of the finished baby food products that Nurture tested
3 contained over 10 ppb lead. Moreover, Danone and Nurture sold finished baby food products
4 containing as much as 10 ppb mercury. But Nurture never issued a recall for these products. Indeed,
5 nothing indicates that Nurture made any changes to its policies or approaches toward heavy metals
6 monitoring to ensure that baby food with this level of heavy metal contamination was not released to
7 the public.

8 80. The guiding light for Nurture and Danone's choices was always money. They chose
9 their infrequent testing and lack of heavy metal specifications policies based on cost. They chose not
10 to inform parents of the presence of heavy metals in their foods because they knew parents would
11 then not purchase their products. They capitalized on the term "organic" that featured prominently
12 on their labels, knowingly exploiting consumers' widespread confusion that "organic" means free of
13 heavy metals. And, they implemented policies of refusing to provide testing results of their products
14 to consumers, even when parents asked, because they knew the effect such information would have
15 on their sales.

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

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

1 83. Plum and Campbell failed to set limits on the amount of heavy metals that could be
2 present in Plum's finished baby food products. From 2007 to at least April 2021, they did not set *any*
3 limits for the amount of lead, arsenic, mercury, cadmium, or aluminum that their finished products
4 could contain.

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

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

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

27 87. Despite not having a comprehensive ingredient testing program to ensure that Plum
28 food marketed for babies was not contaminated with Toxic Heavy Metals, Plum and Campbell/Sun-

1 Maid also did not conduct heavy metal testing on Plum products prior to sale. Plum only first
2 conducted finished product testing in the wake of public reports that exposed Plum baby food
3 products as being contaminated with dangerous levels of heavy metals. Upon information and belief,
4 no rigorous heavy metal testing program on ingredients and finished product was ever implemented
5 and Plum and Campbell/Sun-Maid continued and continue to sell baby food contaminated with
6 elevated levels of heavy metals without first testing to ensure their safety.

7 88. **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-Apple
9 Kale contained 107 ppb total arsenic, 47 ppb inorganic arsenic, 39.3 ppb lead, and 41.5 ppb
10 cadmium. These levels are all highly dangerous for consumption by an infant.

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

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

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

26 92. Internal documents within Sprout confirm that the companies were aware of these
27 issues, even made jokes about it, but took no action to take reasonable care to avoid harm to infants
28 until Congress blew the whistle on Sprout—and then, only after Sprout initially refused to cooperate

1 with a Congressional investigation.

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

5 94. **Walmart.** Walmart sold baby food under a “private” brand called “Parent’s Choice”,
6 which was manufactured by a different supplier but branded, promoted, and sold as a Walmart
7 product. Walmart did not test it for Toxic Heavy Metals whatsoever. Instead, Walmart required
8 certain specifications be met for the products provided by its suppliers, which included some limits of
9 heavy metals. These specifications were not enforced in any way. Walmart did not require the
10 submission of testing from suppliers, nor did it do any of its own testing.

11 95. The only efforts to police Toxic Heavy Metals in their Parent’s Choice baby food
12 involved generic specifications for lead and arsenic—there were no other specifications or limits for
13 other Toxic Heavy Metals—which for most baby food products resulted in there being no limits. The
14 following chart reflects Walmart’s Toxic Heavy Metal specifications prior to December 2018.

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

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

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

24 97. In 2019, as concerns grew over contamination of certain baby foods on the U.S.
25 market, a consortium of the Defendants comprised of Beech-Nut, Plum/Campbell, Gerber, Hain,
26 Nurture, and Sprout, as well as certain interested third party groups such as the Environmental
27 Defense Fund (“EDF”) and HBBF, were formed with the intention “of reducing heavy metals in
28 young children’s food.”

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

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

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

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

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

28 102. HBBF explained:

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

1 will move the needle on this important issue.

2 103. In short, the Defendants opted to continue “self-regulating,” the same self-regulation
3 which exposed—and continued to expose—Plaintiffs to Toxic Heavy Metals in Defendants’ baby
4 foods.

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

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

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

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

106. As one recent study observed, “[t]he implications of heavy metals with regards to

1 children's health have been noted to be more severe compared to adults. The elements' harmful
2 consequences on children health include mental retardation, neurocognitive disorders, behavioral
3 disorders, respiratory problems, cancer and cardiovascular diseases. Much attention should be given
4 to heavy metals because of their high toxicity potential, widespread use, and prevalence." Children
5 and, even more so, babies have higher exposure to metals compared to adults because they consume
6 more food in relation to their body weight and absorb metals more readily than adults by 40 to 90%.

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

14 108. Thus, "the major windows of developmental vulnerability occur during infancy and
15 early childhood due to continuing brain development after birth." In short, even small amounts of
16 exposure to Toxic Heavy Metals can have devastating health outcomes for babies and children.

17 **A. Exposure to Toxic Heavy Metals Has Been Consistently Associated with**
18 **Neurodevelopmental Harm, i.e., Autism and ADHD in Pediatric Populations**

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

28 110. Such conclusions have likewise been reached by a consortium of the country's leading

1 epidemiologists, pediatricians, and medical groups, noting that Toxic Heavy Metals such as lead and
2 mercury are “prime examples of toxic chemicals that can contribute to learning, behavioral, or
3 intellectual impairment, as well as specific neurodevelopmental disorders such as ADHD or autism
4 spectrum disorder.”

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

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

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

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

23 115. Studies have repeatedly observed strong associations between exposure to cadmium
24 and aluminum and neurodevelopmental disorders such as ASD, as observed by a recent study:
25 “Environmental exposure to...cadmium (Cd)... and aluminum (Al) has been associated with
26 neurodevelopmental disorders including autism spectrum disorder (ASD).” For example, a study
27 from 2014 evaluated the body burden of lead, cadmium, and arsenic in children with autism
28 compared to controls and noted that, in addition to lead and arsenic, “our study demonstrated

1 elevation in the levels of...cadmium...in a child with autism,” while an earlier study noted that
2 “autism may be associated with significant alterations of some rare element concentrations, including
3 Cd...” Such results have been confirmed by meta-analyses which “show *significant associations*
4 between ASD and the metals Al [and] Cd.” And, such earlier data is further supported by recent
5 research, with a 2023 systematic review and meta-analysis concluding that “compared with the
6 healthy control group, the ASD group had higher concentrations of Cd, Pb, arsenic, and Hg. These 4
7 heavy metals play different roles in the occurrence and progression of ASD.”

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

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

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

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

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

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

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

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

1 **B. Defendants' Baby Foods Contain Toxic Heavy Metals Capable of Interfering**
2 **with Early Neurodevelopment**

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

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

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

27 127. Similarly, upon information and belief, Defendant Hain was aware of the neurotoxic
28 propensities of lead, arsenic, and mercury at low levels, but proceeded to manufacture and sell Baby

1 Foods containing arsenic and lead levels that, upon information and belief, Hain considered as
2 capable of inflicting neurodevelopmental harm.

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

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

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

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

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

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

1 certain pre-mix minerals and vitamins high in Toxic Heavy Metals or sampling their ingredients from
2 other sources. At the very least, Defendants were under a duty to warn unsuspecting parents of the
3 presence of Toxic Heavy Metals in their Baby Foods.

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

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

18 134. Defendants' baby food products are also defective as manufactured, as they contain
19 detectable Toxic Heavy Metals which are not supposed to be there, by design. Toxic Heavy Metals
20 do not provide any nutritional or therapeutic value to infants or fully-grown humans. They are only
21 poisonous to neurodevelopment. None of these baby food products, by design, should contain Toxic
22 Heavy Metals in them and, thus, to the extent the products contain detectable levels of Toxic Heavy
23 Metals in them, those are manufacturing defects. Based on publicly available data, most of
24 Defendants' baby food products contain some detectable levels of Toxic Heavy Metals in them.
25 However, as the levels of Defendants' baby food products are not known yet, nor do Plaintiffs have a
26 complete list of Defendants' baby food products or their formulations—information that will be
27 obtained through discovery—Plaintiffs cannot identify each baby food product that contained a
28 manufacturing defect. However, Appendix A is a running list of baby food products sold by

1 Defendants.

2 135. If Defendants specifically designed their baby food products to contain Toxic Heavy
3 Metals, meaning their presence was not the product of a manufacturing defect, then the products were
4 defective by design. Toxic Heavy Metals should not be present in foods that are being consumed by
5 infants and products should be designed to not have detectable levels of toxic heavy metal in them.
6 Such designs are easily accomplished, by only using ingredients that contain non-detectable levels of
7 Toxic Heavy Metals and by testing finished products, before release, to ensure they do not contain
8 Toxic Heavy Metals within them. This is possible because there are examples of Defendants'
9 finished products not containing detectable levels of Toxic Heavy Metals—even if, for that same
10 products, there are instances where they did. Thus, Defendants were able to design baby food
11 products to not contain detectable levels of toxic heavy metals, and to the extent that each
12 Defendants' design contemplated there being detectable levels of Toxic Heavy Metals in baby food,
13 the design, itself, was defective. Because Plaintiffs do not know the Defendants' intended design for
14 their baby food products—as there has been no discovery obtained to date concerning product
15 formulation, product/ingredient specifications, and testing methodologies/capabilities—Plaintiffs
16 cannot specify which baby food products were defectively designed versus which ones were not.
17 That said, Appendix A, a running list of the Defendants' baby food products that, with further
18 discovery, may yield information that will allow Plaintiffs to identify whether the product was
19 defectively designed.

20 136. Whether the Defendants' products were defective due to inadequate warnings,
21 manufacturing errors, or by design, the existing publicly available evidence indicates that
22 consumption of Defendants' baby food products can expose infants to Toxic Heavy Metals, and that
23 depending on specific milieu of products consumed by each Plaintiff and each Plaintiff's specific
24 susceptibility and circumstances, Defendants' baby food products contributed to each Plaintiff's
25 Toxic Heavy Metal burden during critical period of infant neurodevelopment. Each Plaintiff, thus,
26 alleges that this cumulative exposure from Defendants' products to Toxic Heavy Metals, substantially
27 contributed to causing neurodevelopmental harm that manifested as ASD and/or ADHD. Moreover,
28 each Plaintiff alleges that had these baby food products not been defective—by having sufficient

1 warnings, being correctly manufactured, and/or designed properly—each Plaintiff would not have
2 been exposed to levels of Toxic Heavy Metals in Defendants’ baby food products that would have
3 contributed to the neurodevelopmental harm that manifested as ASD and/or ADHD.

4 **VIII. Exemplary / Punitive Damages Allegations**

5 137. Defendants’ conduct as alleged herein was done with reckless disregard for human
6 life, oppression, and malice. Defendants’ conduct is particularly reprehensible given that their toxic
7 foods were directed at vulnerable babies—a population group far more susceptible than adults to the
8 neurotoxic dangers of heavy metals.

9 138. Defendants were fully aware of the safety risks of Contaminated Baby Foods,
10 particularly the dangerous potential of Toxic Heavy Metals on neurodevelopment in infants and
11 children. Nonetheless, Defendants deliberately crafted their label, marketing, and promotion to
12 mislead consumers. Indeed, Defendants repeatedly market their baby foods as safe for consumption
13 and go so far as claiming that they adhere to “the strictest standards in the world;” and provide
14 “baby’s food full of nutrition while meeting standards strict enough for tiny tummies,” as well as
15 other statements and representations that hold out their baby foods as safe for consumption by
16 infants. Indeed, each Defendant falsely reassured parents/guardians/caregivers that their baby foods
17 would foster healthy neurodevelopment when consumed even though they knew their baby foods
18 exposed infants’ developing brains to potent neurotoxic heavy metals. In actual fact, as discussed
19 above, Defendants routinely sold Contaminated Baby Foods, regularly flouted their own internal
20 limits of Toxic Heavy Metals and failed to disclose to consumers that their products contained such
21 dangerous contaminants.

22 139. This was not done by accident or through some justifiable negligence. Rather,
23 Defendants knew they could profit by convincing consumers that their baby foods were healthy and
24 safe for infants, and that full disclosure of presence and/or risks of the Toxic Heavy Metals present in
25 the baby foods would limit the amount of money Defendants would make selling the products.
26 Defendants’ object was accomplished not only through a misleading label, but through a
27 comprehensive scheme of selective misleading research and testing, failure to test, false advertising,
28 and deceptive omissions as more fully alleged throughout this Complaint.

1 Parents/guardians/caregivers were denied the right to make an informed decision about whether to
2 purchase Defendants' baby food for their babies without knowing the full risks attendant to that use.
3 Such conduct was done with conscious disregard of Plaintiffs' welfare and rights.

4 **CAUSES OF ACTION**

5 **I. COUNT I: STRICT PRODUCTS LIABILITY – FAILURE TO WARN**

6 140. Plaintiffs incorporate by reference each allegation set forth in preceding paragraphs as
7 if fully stated herein.

8 141. At all relevant times, Defendants engaged in the business of researching, testing,
9 developing, designing, manufacturing, labeling, marketing, selling, inspecting, distributing, and
10 promoting baby foods, which are defective and unreasonably dangerous to consumers, including
11 Plaintiffs, because they do not contain adequate warnings or instructions concerning the dangerous
12 characteristics of baby foods in the form of the presence of Toxic Heavy Metals. These actions were
13 under the ultimate control and supervision of Defendants. At all relevant times, Defendants
14 registered, researched, manufactured, distributed, marketed, and sold baby foods and aimed at a
15 consumer market.

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

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

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

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

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

20 147. At all relevant times, Defendants' Contaminated Baby Foods reached the intended
21 consumers, handlers, and users or other persons coming into contact with these products, including
22 Plaintiffs, without substantial change in their condition as manufactured, sold, distributed, labeled,
23 and marketed by Defendants.

24 148. Plaintiffs were exposed to the Toxic Heavy Metals in Defendants' Contaminated Baby
25 Foods without knowledge of the potential for such exposure to Toxic Heavy Metals from
26 consumption of the products and the dangerous characteristics of the toxins.

27 149. At all relevant times, Plaintiffs were exposed to the Toxic Heavy Metals in the
28 Defendants' Contaminated Baby Foods while consuming the foods for their intended or reasonably

1 foreseeable purposes, without knowledge of their dangerous characteristics.

2 150. Plaintiffs could not have reasonably discovered the defects and risks associated with
3 exposure to the Toxic Heavy Metals in the Contaminated Baby Foods prior to or at the time of
4 Plaintiffs consuming those foods. Plaintiffs relied upon the skill, superior knowledge, and judgment
5 of Defendants to know about and disclose serious health risks associated with exposure to the toxins
6 in Defendants' products.

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

17 152. This alleged failure to warn is not limited to the information contained on
18 Contaminated Baby Foods labeling. The Defendants were able, in accord with federal law, to
19 comply with relevant state law by disclosing the known risks associated with exposure to Heavy
20 Metals in Contaminated Baby Foods through other non-labeling mediums, i.e., promotion,
21 advertisements, public service announcements, and/or public information sources. But the
22 Defendants did not disclose these known risks through any medium. The ability to provide such
23 warnings is not prohibited by any federal law.

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

28 154. Had Defendants provided adequate warnings and instructions and properly disclosed

1 and disseminated the risks associated with exposure to the toxins in their Contaminated Baby Foods,
2 Plaintiffs could have avoided the risk of developing injuries and could have obtained or used
3 alternative products. However, as a result of Defendants' concealment of the dangers posed by the
4 Toxic Heavy Metals in their Contaminated Baby Foods, Plaintiffs could not have averted their
5 exposures.

6 155. Defendants' conduct, as described above, was reckless. Defendants risked the lives of
7 babies and children, including Plaintiffs, with knowledge of the safety problems associated with
8 Contaminated Baby Foods, and suppressed this knowledge from the general public. Defendants
9 made conscious decisions not to warn or inform the unsuspecting public.

10 156. The Defendants' lack of adequate warnings and instructions accompanying their
11 Contaminated Baby Foods caused each Plaintiff's injuries.

12 157. As a direct and proximate result of the Defendants' failure to provide an adequate
13 warning of the risks of exposure to the Toxic Heavy Metals in their Contaminated Baby Foods,
14 Plaintiffs have been injured, sustained severe and permanent pain, suffering, disability, impairment,
15 loss of enjoyment of life, economic loss and damages including, but not limited to past and future
16 medical expenses, lost income, and other damages.

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

20 **II. COUNT II: STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT**

21 159. Plaintiffs incorporate by reference each allegation set forth in preceding paragraphs as
22 if fully stated herein.

23 160. At all times herein mentioned, Defendants designed, manufactured, tested, marketed,
24 sold, handled, and distributed the Contaminated Baby Foods consumed by Plaintiffs.

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

28 162. At all relevant times, the Contaminated Baby Foods consumed by Plaintiffs were used

1 in a manner that was foreseeable and intended by Defendants.

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

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

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

16 166. This manufacturing defect caused each Plaintiff to be exposed to Toxic Heavy Metals
17 through ingestion of the Contaminated Baby Foods which, in turn, caused neurodevelopmental harm
18 that manifested as ASD and/or ADHD.

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

23 168. Defendants have intentionally and recklessly manufactured the Contaminated Baby
24 Foods with wanton and willful disregard for the rights and health of Plaintiffs, and with malice,
25 placing their economic interests above the health and safety of Plaintiffs.

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

1 169. As a direct and proximate result of the Defendants' defective manufacture of the
2 Contaminated Baby Foods, Plaintiffs have been injured, sustained severe and permanent pain,
3 suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but
4 not limited to medical expenses, lost income, and other damages.

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

8 **III. COUNT III: STRICT PRODUCTS LIABILITY – DESIGN DEFECT**

9 171. Plaintiffs incorporate by reference each allegation set forth in preceding paragraphs as
10 if fully stated herein.

11 172. At all times herein mentioned, Defendants designed, manufactured, tested, marketed,
12 sold, handled, and distributed the Contaminated Baby Foods consumed by Plaintiffs. These actions
13 were under the ultimate control and supervision of Defendants.

14 173. At all relevant times, Defendants' Baby Food products were designed and labeled in
15 an unsafe, defective, and inherently dangerous manner that was dangerous for use or consumption by
16 infants and babies, including Plaintiffs.

17 174. Defendants' Contaminated Baby Food products as researched, tested, developed,
18 designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants
19 were defective in design and formulation in that, when they were placed into the stream of
20 commerce, they were unreasonably dangerous and dangerous to an extent beyond that which an
21 ordinary consumer would contemplate.

22 175. Defendants' Contaminated Baby Food products, as researched, tested, developed,
23 designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants
24 were defective in design and formulation in that, when they left the hands of Defendants, the
25 foreseeable risks exceeded the alleged benefits associated with their design and formulation.

26 176. At all relevant times, the Contaminated Baby Food products consumed by Plaintiffs
27 were expected to and did reach Plaintiffs without a substantial change in its condition as designed,
28 manufactured, handled, distributed, and sold by Defendants.

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

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

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

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

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

18 D. Exposure to the Toxic Heavy Metals in Defendants' Contaminated Baby Food
19 products present a risk of harmful effects that outweigh any potential utility stemming from
20 their use;

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

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

26 179. Plaintiffs consumed Defendants' Contaminated Baby Food products in an intended or
27 reasonably foreseeable manner without knowledge of their dangerous characteristics.

28 180. Defendants' Contaminated Baby Food products were and are more dangerous than

1 alternative products, and Defendants could have designed their Contaminated Baby Food products to
2 avoid harm to children. Indeed, at the time Defendants designed the Contaminated Baby Food
3 products, the state of the industry's scientific knowledge was such that a less risky design or
4 formulation was attainable.

5 181. At the time the Contaminated Baby Food products left Defendants' control, there was
6 a practical, technically feasible, and safer alternative design that would have prevented the harm
7 without substantially impairing the reasonably anticipated or intended function of Defendants'
8 Contaminated Baby Foods.

9 182. Defendants intentionally and recklessly defectively designed the Contaminated Baby
10 Foods with wanton and willful disregard for the rights and health of Plaintiffs, and with malice,
11 placing their economic interests above the health and safety of Plaintiffs.

12 183. The design defects in Defendants' Contaminated Baby Foods were substantial factors
13 in causing Plaintiffs' injuries.

14 184. As a direct and proximate result of the Defendants' defective design of the
15 Contaminated Baby Foods, Plaintiffs have been injured, sustained severe and permanent pain,
16 suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but
17 not limited to medical expenses, lost income, and other damages.

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

21 **IV. COUNT IV: NEGLIGENCE – FAILURE TO WARN**

22 186. Plaintiffs incorporate by reference each allegation set forth in preceding paragraphs as
23 if fully stated herein.

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

1 supervision of Defendants.

2 188. Defendants researched, developed, designed, tested, manufactured, inspected, labeled,
3 distributed, marketed, promoted, sold, and otherwise released into the stream of commerce their
4 Contaminated Baby Foods, and in the course of same, directly advertised or marketed the products to
5 consumers and end users, including Plaintiffs, and therefore had a duty to warn of the risks associated
6 with the presence of and exposure to Toxic Heavy Metals from consumption of Contaminated Baby
7 Foods.

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

15 190. At the time of manufacture, Defendants could have provided warnings regarding the
16 presence of and risks of exposure to Toxic Heavy Metals from consumption of Contaminated Baby
17 Foods because they knew or should have known exposure to Toxic Heavy Metals from consumption
18 of Contaminated Baby Foods was dangerous, harmful and injurious when the Contaminated Baby
19 Foods were consumed by Plaintiffs in a reasonably foreseeable manner.

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

23 192. Defendants knew or should have known that exposure to Toxic Heavy Metals from
24 consumption of Contaminated Baby Foods posed a risk of harm, but failed to exercise reasonable
25 care to warn of the dangerous risks associated with use and exposure to the toxins in the products.
26 The dangerous propensities of exposure to Toxic Heavy Metals from consumption of the
27 Contaminated Baby Foods, as described above, were known to Defendants, or scientifically
28 knowable to Defendants through appropriate research and testing by known methods, at the time they

1 distributed, supplied, or sold the products, and were not known to end users and consumers, such as
2 the Plaintiffs.

3 193. At all relevant times, Plaintiffs were exposed to Toxic Heavy Metals through
4 consumption of the Contaminated Baby Foods while using the products for their intended or
5 reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

6 194. Defendants knew or should have known that the non-extant warnings disseminated
7 with their Contaminated Baby Foods were inadequate, failed to communicate adequate information
8 on the presence of and dangers of exposure to toxins contained therein, and failed to communicate
9 warnings and instructions that were appropriate and adequate to render the products safe for their
10 ordinary, intended and reasonably foreseeable uses.

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

22 196. A reasonable company under the same or similar circumstance would have warned
23 and instructed of the dangers of exposure to Toxic Heavy Metals from consumption of Contaminated
24 Baby Foods.

25 197. This alleged failure to warn is not limited to the information contained on the labeling
26 of Defendants' Contaminated Baby Foods. Defendants were able, in accord with federal law, to
27 comply with relevant state law by disclosing the known risks associated with exposure to Toxic
28 Heavy Metals from consumption of Contaminated Baby Foods through other non-labeling mediums,

1 i.e., promotion, advertisements, public service announcements, and/or public information sources.
2 But the Defendants did not disclose these known risks through any medium.

3 198. Furthermore, Defendants possess a First Amendment Right to make truthful
4 statements about the products they sell, and no law could lawfully restrict that constitutional right.

5 199. Had Defendants provided adequate warnings and instructions and properly disclosed
6 and disseminated the risks associated with the presence of and exposure to Toxic Heavy Metals in the
7 Contaminated Baby Foods, Plaintiffs could have avoided the risk of developing injuries and could
8 have obtained or used alternative products. However, as a result of Defendants' concealment of the
9 dangers posed by their Contaminated Baby Foods, Plaintiffs could not have averted their injuries.

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

14 201. The Defendants' lack of adequate warnings and instructions accompanying their
15 Contaminated Baby Foods were a substantial factor in causing Plaintiffs' injuries.

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

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

24 **V. COUNT V: NEGLIGENCE – MANUFACTURING**

25 204. Plaintiffs incorporate by reference each allegation set forth in preceding paragraphs as
26 if fully stated herein.

27 205. At all relevant times, the Defendants manufactured, tested, marketed, sold, and
28 distributed the Contaminated Baby Foods that Plaintiffs consumed.

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

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

7 208. The Defendants knew or, by the exercise of reasonable care, should have known,
8 ordinary consumers such as Plaintiffs would not have realized the potential risks and dangers of
9 exposure to Toxic Heavy Metals from consumption of Contaminated Baby Foods.

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

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

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

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

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

20 210. A reasonable manufacturer under the same or similar circumstances would have
21 implemented appropriate manufacturing procedures to better ensure the quality and safety of their
22 product.

23 211. Plaintiffs were harmed directly and proximately by the Defendants' failure to use
24 reasonable care in the manufacture of their Contaminated Baby Foods. Such harm includes exposure
25 to Toxic Heavy Metals, which can cause or contribute to interference with early neurodevelopment
26 which manifests as ASD, ADHD, and related *sequelae*.

27 212. Defendants' improper manufacturing of Baby Foods was willful, wanton, malicious,
28 and conducted with reckless disregard for the health and safety of users of the Contaminated Baby

1 Foods, including Plaintiffs.

2 213. The defects in Defendants' Contaminated Baby Foods were substantial factors in
3 causing Plaintiffs' injuries.

4 214. As a direct and proximate result of the Defendants' improper manufacturing of
5 Contaminated Baby Foods, Plaintiffs have been injured, sustained severe and permanent pain,
6 suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but
7 not limited to past and future medical expenses, lost income, and other damages.

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

11 **VI. COUNT VI: NEGLIGENCE – PRODUCT DESIGN**

12 216. Plaintiffs incorporate by reference each allegation set forth in preceding paragraphs as
13 if fully stated herein.

14 217. Defendants knew or, by the exercise of reasonable care, should have known, ordinary
15 consumers such as Plaintiffs would not have realized the potential risks and dangers of Contaminated
16 Baby Foods.

17 218. The Defendants owed a duty to all reasonably foreseeable users to design a safe
18 product.

19 219. The Defendants breached their duty by failing to use reasonable care in the design of
20 Contaminated Baby Foods because the products exposed babies to Toxic Heavy Metals.

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

24 221. The Defendants breached their duty by failing to use reasonable care in the design of
25 Contaminated Baby Foods by negligently designing and formulation, in one or more of the following
26 ways:

27 A. When placed in the stream of commerce, Defendants' Contaminated Baby
28 Foods were defective in design and formulation, and, consequently, dangerous to an extent

1 beyond that which an ordinary consumer would contemplate;

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

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

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

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

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

18 222. Defendants knew or should have known at the time of marketing Contaminated Baby
19 Foods that exposure to Toxic Heavy Metals contained in the Baby Foods could result in interference
20 with early neurodevelopment that that manifests as ASD, ADHD and other severe illnesses and
21 injuries.

22 223. Defendants, by design, did not conduct adequate post-marketing surveillance of their
23 Contaminated Baby Foods.

24 224. Defendants could have employed safer alternative designs and formulations. For
25 example, the Defendants could have avoided use of certain ingredients contaminated with Toxic
26 Heavy Metals, avoided using pre-mix vitamins contaminated with Toxic Heavy Metals, and/or
27 sampled their ingredients from other sources.

28 225. The Defendants breached their duty by failing to use reasonable care by failing to use

1 cost effective, reasonably feasible alternative designs. There was a practical, technically feasible, and
2 safer alternative design that would have prevented the harm without substantially impairing the
3 reasonably anticipated or intended function of Defendants' Contaminated Baby Foods.

4 226. A reasonable company under the same or similar circumstances would have designed
5 a safer product.

6 227. Plaintiffs were harmed directly and proximately by the Defendants' failure to use
7 reasonable care in the design of their Contaminated Baby Foods. Such harm includes exposure to
8 Toxic Heavy Metals, which can cause or contribute to interference with neurodevelopment that
9 manifests as ASD, ADHD, and related *sequelae*.

10 228. Defendants' defective design of Contaminated Baby Foods was willful, wanton,
11 malicious, and conducted with reckless disregard for the health and safety of consumers of the Baby
12 Foods, including Plaintiffs.

13 229. The defects in Defendants' Contaminated Baby Foods were substantial factors in
14 causing Plaintiffs' injuries.

15 230. As a direct and proximate result of the Defendants' negligent design of the
16 Contaminated Baby Foods, Plaintiffs have been injured, sustained severe and permanent pain,
17 suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but
18 not limited to past and future medical expenses, lost income, and other damages.

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

22 **VII. COUNT VII: GENERAL NEGLIGENCE**

23 232. Plaintiffs incorporate by reference each allegation set forth in preceding paragraphs as
24 if fully stated herein.

25 233. Plaintiffs plead claims for negligence under all theories that may be actionable under
26 any applicable state laws.

27 234. Defendants owed Plaintiffs a duty to act with reasonable care.

28 A. Defendants owed a duty because they distributed and promoted their products

1 as safe for children to consume.

2 B. Defendants owed a duty because their conduct created a risk of harm to
3 Plaintiffs and caused Plaintiffs actual harm.

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

6 D. Defendants owed a duty because they designed, manufactured, controlled,
7 distributed, and sold their products to Plaintiffs.

8 235. Defendants breached their duty to Plaintiffs.

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

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

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

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

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

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

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

28 G. Defendants, by design, did not conduct adequate post-marketing surveillance

1 of their Contaminated Baby Food products which would have alerted the public to risks; and

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

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

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

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

14 237. Defendants knew or should have known that their products contained detectable levels
15 of heavy metals that created an unreasonable risk of harm to children who consumed their products.

16 238. At all relevant times, the Defendants knew or should have known that the Products
17 were unreasonably dangerous and defective when put to their reasonably anticipated use.

18 239. As a proximate result of Defendants' negligence, Plaintiffs have been injured,
19 sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life,
20 economic loss, and damages including, but not limited to past and future medical expenses, lost
21 income, and other damages.

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

25 **JURY TRIAL DEMAND**

26 241. Plaintiff demands a trial by jury on all the triable issues within this pleading.

27 **PRAYER FOR RELIEF**

28 242. **WHEREFORE**, each Plaintiff requests that the Court enter judgment in Plaintiffs'

1 favor and against the Defendants for:

- 2 a. actual or compensatory damages in such amount to be determined at trial and as
3 provided by applicable law;
- 4 b. exemplary and punitive damages sufficient to punish and deter the Defendants and
5 others from future wrongful practices;
- 6 c. pre-judgment and post-judgment interest;
- 7 d. costs including reasonable attorneys' fees, court costs, and other litigation expenses;
8 and
- 9 e. any other relief the Court may deem just and proper.

10 Dated: July 15, 2024

Respectfully submitted,

11 /s/ R. Brent Wisner

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