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15 **UNITED STATES DISTRICT COURT**
 16 **FOR THE MIDDLE DISTRICT OF FLORIDA**

17 IN RE: BABY FOOD PRODUCTS LIABILITY
 18 LITIGATION

Hon.
COMPLAINT AND JURY DEMAND
Case no.: 8:26-cv-299

19 This Document Relates To:
 20 SAFAA CLERMONT, on Behalf of E.E., A
 21 MINOR,

Plaintiff,

v.

22 Gerber Products Company, Hain Celestial
 23 Group, Inc., Nestlé USA, Inc., Nestlé Enterprises
 24 S.A., Société des Produits Nestlé S.A., and
 25 DOES 1 through 10 inclusive

Defendants.

INTRODUCTION

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

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

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

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

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

8 **PARTIES**

9 **I. Plaintiffs**

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

13 6. Plaintiff consumed baby foods manufactured and/or sold by Gerber Products
14 Company, and Hain Celestial Group, Inc.

15 7. The baby foods manufactured by Defendant Gerber and consumed by Plaintiff
16 were manufactured at the direction of, and/or under the control of, and/or according to the
17 specification of, and/or with input from the parent companies, Nestlé USA, Inc., Nestlé
18 Enterprises S.A., and Société des Produits Nestlé S.A.

19 8. The baby foods manufactured by Defendant Nurture and consumed by Plaintiff
20 were manufactured at the direction of, and/or under the control of, and/or according to the
21 specification of, and/or with input from the parent companies, Danone North America, PBC,
22 and Danone Nutricia Nederland BV. Plaintiff is currently investigating which Danone entity is
23 involved and Plaintiff will amend his complaint to identify the correct Danone entity.

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

28 10. The baby foods manufactured by Defendant Sprout Foods, Inc. and consumed by

1 Plaintiff were manufactured at the direction of, and/or under the control of, and/or according to
2 the specification of, and/or with input from the parent company, Neptune Wellness Solutions.

3 11. Plaintiff alleges that as a direct and proximate result of Plaintiff's exposure to
4 Toxic Heavy Metals from consumption of Defendants' Contaminated Baby Foods, they
5 suffered significant harm, conscious pain and suffering, physical injury and bodily impairment
6 including, but not limited to, brain injury manifesting as the neurodevelopmental disorder ASD,
7 other permanent physical deficits, permanent bodily impairment, and other *sequelae*. Plaintiff's
8 injuries required medical intervention to address the adverse neurological effects and damage
9 caused by exposure to Toxic Heavy Metals in Defendants' Contaminated Baby Foods.

10 Additionally, Plaintiff has suffered severe mental and physical pain, including but not limited
11 to, pain, mental suffering, loss of enjoyment of life, disfigurement, physical impairment,
12 inconvenience, grief, anxiety, humiliation, and emotional distress and has and will sustain such
13 injuries, along with economic loss due to medical expenses and living-related expenses as a
14 result of lifestyle changes, into the future, as determined by the Trier of Fact.

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

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

1 **II. Defendants**

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

3 15. Gerber Products Company (“Gerber”)

4 16. Hain Celestial Group, Inc. (“Hain”)

5 17. Nestlé USA, Inc. (“Nestlé USA”)

6 18. Nestlé Enterprises S.A. (“Nestlé Enterprises”)

7 19. Société des Produits Nestlé S.A. (“SPN”)

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

16 21. Gerber is part of the Nestlé family of companies ultimately owned by Nestlé
17 S.A. (“Nestlé”), a citizen of Switzerland, with its principal place of business located at Avenue
18 Nestlé 55, 1800 Vevey, Switzerland. Nestlé is a global food and beverage company with more
19 than 2,000 brands. Nestlé sells baby foods under its subsidiary, Gerber, a wholly owned
20 subsidiary of Nestlé Holdings, Inc. (“NHI”), a citizen of Delaware and Virginia with its
21 principal place of business located at 1812 N. Moore Street, Arlington, Virginia 22209, which
22 is in turn a wholly owned subsidiary of Nestlé S.A.

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

27 23. Along with Gerber, other Nestlé entities were directly involved in the content
28 and quality of the Gerber Baby Foods at issue, including decisions and actions related to

1 sourcing ingredients, setting limits for Toxic Heavy Metals, and testing for Toxic Heavy
2 Metals.

3 24. Nestlé USA, Inc. (“Nestle USA”), a wholly owned subsidiary of Nestlé S.A., is a
4 Delaware corporation with its headquarters located at 1812 North Moore Street, Arlington,
5 Virginia 22209. First incorporated in 1920, Nestlé USA has approximately 36,000 employees
6 and is the parent company of Gerber Products Company.

7 25. Plaintiff incorporates by reference the allegations in Paragraphs 19-22 from the
8 Amended Master Complaint (Docket No. 451) of MDL 3101, currently in active litigation in
9 the Northern District of California.

10 26. On information and belief, other Nestlé entities were directly involved in the
11 content and quality of the Gerber Baby Foods at issue, including decisions and actions related
12 to sourcing ingredients, setting limits for Toxic Heavy Metals, and testing for Toxic Heavy
13 Metals. Information discovered to date in this litigation and concurrent state-court litigation
14 indicates that Gerber undertook the tortious conduct alleged herein at the direction of or in
15 tandem with Nestlé entities, but discovery has not enabled Plaintiffs to specifically identify all
16 relevant Nestlé entities within the complex corporate chain. Plaintiffs reserve all rights to
17 pursue claims against additional Nestlé entities that further discovery may reveal.

18 27. For the purposes of this Complaint, unless specifically stated otherwise, Nestlé
19 USA, Nestlé Enterprises S.A., SPN, and any other responsible Nestlé entities shall be
20 collectively referred to as “Nestlé entities.” Further, allegations related to Gerber apply equally
21 to Nestlé, as each Defendant exercised authority and control over the sale, manufacture, and
22 distribution of Gerber’s Contaminated Baby Foods at issue in this MDL. At all relevant times,
23 the named Nestlé entities have conducted business and derived substantial revenue from the
24 manufacturing, advertising, distributing, selling, and marketing of Baby Foods within this
25 judicial district and throughout the United States.

26 28. The Hain Celestial Group, Inc. (“Hain”) is a citizen of Delaware and New York
27 with its principal place of business located at 1111 Marcus Ave., Lake Success, New York
28 11042. Hain sells baby foods under the brand name Earth’s Best Organics. Hain offers infant

1 and baby formula and foods as well as toddler foods covering products from “organic infant
2 cereal” to “organic snacks for toddlers and kids on the go.” At all relevant times, Hain has
3 conducted business and derived substantial revenue from its manufacturing, advertising,
4 distributing, selling, and marketing of Baby Foods within this judicial district and throughout
5 the United States.

6 **JURISDICTION AND VENUE**

7 29. Plaintiff(s) file this Complaint pursuant to CMO No. 5, and are to be bound by
8 the rights, protections, and privileges, and obligations of that CMO and other Order of the
9 Court. Further, in accordance with CMO No. 5, Plaintiff(s) hereby designate the United States
10 District Court for the Middle District of Florida as Plaintiff’s designated venue (“Original
11 Venue”). Plaintiff makes this selection based upon one (or more) of the following factors
12 (check the appropriate box(es)):

13 Plaintiff currently resides in Winter Haven, Florida.

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

15 The Original Venue is a judicial district in which Defendant _____ resides, and
16 all Defendants are residents of the State in which the district is located (28 U.S.C.
17 1391(b)(1)).

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

20 There is no district in which an action may otherwise be brought under 28 U.S.C.
21 1391, and the Original Venue is a judicial district in which Defendant _____ is subject
22 to the Court’s personal jurisdiction with respect to this action (28 U.S.C. 1391 (b)(3)).

23 Other reason (please explain): _____

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

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

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

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

25 **II. Congressional Investigation Finds Substantial Presence of Heavy Metals in Baby** 26 **Foods Manufactured and/or Sold by Defendants, Sparking National Outrage**

27 38. On February 4, 2021, and September 29, 2021, respectively, the U.S. House of
28 Representatives’ Subcommittee on Economic and Consumer Policy, Committee on Oversight

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

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

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

23 41. **Hain (Earth’s Best Organic).** Hain sold finished baby food products containing
24 as much as 129 ppb inorganic arsenic. Hain typically only tested its ingredients, not finished
25 products. Documents show that Hain used ingredients testing as high as 309 ppb arsenic. Hain
26 used ingredients containing as much as 352 ppb lead. Hain used many ingredients with high
27 lead content, including 88 that tested over 20 ppb lead and six that tested over 200 ppb lead.
28 And, Hain does not even test for mercury in its baby food. However, independent testing by

1 HBBF of Hain’s Baby Foods confirm that Hain’s products contain as much as 2.4 ppb of
2 mercury.

3 42. The metal concentrations discussed above and further below surpass the limits
4 allowed by U.S. regulatory agencies. There are no FDA final regulations governing the
5 presence of Toxic Heavy Metals in the majority of Baby Foods with the exception of 100 ppb
6 inorganic arsenic in infant rice cereal and some recently finalized limits for lead in certain baby
7 food categories. To the extent such regulations exist, the quantities of Toxic Heavy Metals in
8 Defendants’ Baby Foods exceed any permissible FDA levels. To be sure, the FDA has set the
9 maximum contaminant levels (“MCL”) in bottled water at 10 ppb inorganic arsenic, 5 ppb lead,
10 and the EPA has capped the allowable level of mercury in drinking water at 2 ppb. However,
11 these limits were created in reference to *adult* exposure, not infants. Compared to these
12 thresholds, the test results of the Defendants’ baby foods and their ingredients are multiple folds
13 greater than the permitted metal levels. They are also far greater than permitted by the FDA’s
14 final guidance for lead, issued January 6, 2025, which sets limits at 10 or 20 ppb for baby foods
15 (10 ppb for fruits, 10 ppb for single or mixed vegetable purees/puddings, 20 ppb for single
16 ingredient root vegetables, and 20 ppb for dry cereals) and 10 or 20 ppb for juices (10 ppb for
17 apple juice or single-strength juice and 20 ppb for juice blends containing apple juice), and the
18 FDA’s proposed limit for arsenic in apple juice (10 ppb). Moreover, compounding these
19 troubling findings, the Defendants set internal limits for the presence of Toxic Heavy Metals in
20 their foods that were, themselves, dangerously high and then routinely failed to abide by those
21 inadequate standards, as discussed below.

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

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

27 44. Several factors drive the Toxic Heavy Metal contamination of Defendants’ baby
28 foods, all of which are within Defendants’ control.

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

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

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

23 48. *Fourth*, Defendants did not routinely adhere to their own internal metal
24 specifications or standards, allowing contaminated ingredients and finished products to be
25 released as “exceptional releases” or other simpler terminology. This resulted in ingredients
26 being used and baby foods manufactured and sold that contained levels of Toxic Heavy Metals
27 far higher than what was internally set by Defendants. In other instances, Defendants would
28 test products that had been put on the market after-the-fact, learn about the products containing

1 extremely high levels of Toxic Heavy Metals, and then take no action to recall the product or
2 warn consumers about the issue.

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

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

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

19 52. Upon information and belief, Beech-Nut went so far as to manipulate testing
20 practices by continually re-testing ingredients that tested above internal specs until obtaining a
21 result that was at or below the internal specs, knowing full well that the ingredient was
22 nonetheless contaminated.

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

1 because they were readily available.

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

21 55. Gerber and Nestlé entities would also audit and re-test Toxic Heavy Metal
22 results submitted by suppliers, and find that the certification from suppliers were incorrect or
23 false. Gerber and Nestlé entities would nonetheless use the certified results and release
24 products despite the ingredients not meeting specifications or being safe for infant consumption.

25 56. Gerber and Nestlé entities often used high-arsenic ingredients, for example,
26 using 67 batches of rice flour that had tested over 90 ppb inorganic arsenic. Furthermore,
27 Gerber and Nestlé entities regularly sold baby food products testing over 100 ppb arsenic, at
28 times reaching 116 ppb, and their average rice cereal product contained 87.43 ppb inorganic

1 arsenic. Indeed, this is why Congress noted that “Gerber’s organic rice cereal is dangerous...”
2 In other instances, Gerber permitted as much as 300 ppb of arsenic in the rice flour ingredient
3 used to manufacture its U.S. baby foods, notwithstanding the fact that Gerber often
4 implemented stricter standards for baby foods sold in other countries.

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

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

18 59. Moreover, compounding these troubling findings, Gerber and Nestlé entities
19 historically only tested certain ingredients of its baby food products and only occasionally tested
20 the finished products consumed by babies. It was not until recently that Gerber and Nestlé
21 entities started to implement finished product testing on a more regular basis.

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

26 61. **Hain.** Hain did not test its baby food products for heavy metals until 2020 (rice
27 cereal) and 2021 (other baby food). Instead, Hain tested some ingredients used in their foods
28 (but not all ingredients). Ingredients were required to meet specific specifications for each

1 specific ingredient. Those specifications, however, would change wildly without explanation.
2 For example, prior to August 2014, Hain's lead specification for Oat Flour was 200 ppb. Then it
3 was reduced to 50 ppb for four months, went back up to 100 ppb for three months, went back
4 up to 200 ppb for a month, came down to 20 ppb for seven months, went to 25 ppb for six
5 months, and then went back to 200 ppb for the next fourteen months. When asked about this
6 seemingly chaotic shifting of specifications, Hain could not explain it.

7 62. Hain would routinely accept ingredients that tested above specifications and use
8 them in baby foods anyway. These "exceptional" releases were made because there were no
9 FDA regulations specifically preventing them.

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

27 64. Hain's inept process of monitoring the safety of their baby foods resulted in
28 products being sold that contained Toxic Heavy Metals, and this was done with full knowledge

1 of the risks. When asked why Hain did not warn consumers of the Toxic Heavy Metals in their
2 foods, Hain responded that if they warned, people would not buy their products.

3 65. **Nurture.** Since 2006, Defendant Nurture, under the name Happy Family
4 Organics, has sold a wide variety of baby food products. It was not until 2013—seven years
5 after sales began— and after the Danone acquisition, that Nurture and Danone entities started
6 testing its finished baby food products for lead. This testing, however, remained infrequent and
7 occurred only after the products had been released to the public—not as a condition of product
8 release. Indeed, as of July of 2021, Nurture was still not testing every batch or lot of its baby
9 food products for heavy metals and was not including heavy metal testing as a condition of
10 release.

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

25 67. And yet, all the while, Nurture and Danone entities knew that toxic heavy metals
26 in their baby food could cause brain damage in children. Not only did Nurture and Danone
27 entities know of the dangers heavy metals in their food posed to children, they also trained their
28 employees on that specific risk. For example, Nurture and Danone entities knew that dangerous

1 levels of arsenic existed in the rice that served as the base for many of its baby food products.
2 Despite this knowledge, Nurture never removed rice from its products.

3 68. But in full view of this knowledge and with full understanding of their
4 lackadaisical ingredient oversight approach, Nurture and Danone entities chose to rarely test
5 their finished products for toxic heavy metals. And when they did test their products, they sold
6 them regardless of what the tests showed. For example, Danone entities and Nurture sold baby
7 foods after tests showed they contained as much as 180 ppb inorganic arsenic. Over 25% of the
8 products Nurture tested before sale contained over 100 ppb inorganic arsenic. Nurture's testing
9 shows that the typical baby food product it sold contained 60 ppb inorganic arsenic. Danone
10 entities and Nurture sold finished baby food products that tested as high as 641 ppb lead.
11 Almost 20% of the finished baby food products that Nurture tested contained over 10 ppb lead.
12 Moreover, Danone entities and Nurture sold finished baby food products containing as much as
13 10 ppb mercury. But Nurture never issued a recall for these products. Indeed, nothing indicates
14 that Nurture made any changes to its policies or approaches toward heavy metals monitoring to
15 ensure that baby food with this level of heavy metal contamination was not released to the
16 public.

17 69. The guiding light for Nurture and Danone entities' choices was always money.
18 They chose their infrequent testing and lack of heavy metal specifications policies based on
19 cost. They chose not to inform parents of the presence of heavy metals in their foods because
20 they knew parents would then not purchase their products. They capitalized on the term
21 "organic" that featured prominently on their labels, knowingly exploiting consumers'
22 widespread confusion that "organic" means free of heavy metals. And, they implemented
23 policies of refusing to provide testing results of their products to consumers, even when parents
24 asked, because they knew the effect such information would have on their sales.

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

28 71. Despite Plum's public facing statements that "little ones deserve the very best

1 food from the very first bite” and despite understanding that environmental toxins like heavy
2 metals can cause neurodevelopmental disorders in children, Plum and Campbell/Sun-Maid did
3 very little to ensure that the Plum baby food products marketed for consumption by children are
4 not contaminated with dangerous levels of heavy metals. For example, though Plum and
5 Campbell/Sun-Maid knew that the heavy metal contents of the ingredients used in its products
6 varied by growing region and supplier, they did not undertake an effort to source ingredients
7 with the lowest amount of heavy metals available. And, despite knowing that certain
8 ingredients carry a higher risk for heavy metal contamination, Plum and Campbell/Sun-Maid
9 did not reformulate their products to ensure that they were being made with the lowest
10 achievable amount of heavy metals.

11 72. Plum and Campbell failed to set limits on the amount of heavy metals that could
12 be present in Plum’s finished baby food products. From 2007 to at least April 2021, they did
13 not set *any* limits for the amount of lead, arsenic, mercury, cadmium, or aluminum that their
14 finished products could contain.

15 73. Plum and Campbell also failed to set limits on the amount of heavy metals that
16 could be present in the ingredients used in Plum’s baby food products. Prior to 2016, they did
17 not set limits for the amount of heavy metals that could be present in the ingredients used in
18 Plum products. When Plum and Campbell did begin to implement heavy metal limits for Plum
19 ingredients (in or around 2017), it did so only for lead, arsenic, and cadmium. As of April
20 2021, Plum and Campbell still had no limits for the amount of mercury and aluminum that
21 could be in the ingredients used in their baby food products.

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

28 75. Plum and Campbell/Sun-Maid also conducted very little oversight of their co-

1 manufacturers to ensure that the heavy metal limits for ingredients used in Plum products were
2 adhered to. For example, prior to 2017, Plum and Campbell did not require the ingredient
3 suppliers they contracted with to submit heavy metal testing data but instead relied on supplier
4 assurances that the ingredients did not contain heavy metals and/or complied with all
5 government regulations regarding heavy metals. When Plum and Campbell/Sun-Maid did
6 begin to require testing on some of the ingredients used in its products for lead and arsenic,
7 those efforts were scattershot and did not extend to all lots of all ingredients used in Plum baby
8 food products. Where verification testing was conducted on ingredients, it was often done in an
9 unaccredited lab.

10 76. Despite not having a comprehensive ingredient testing program to ensure that
11 Plum food marketed for babies was not contaminated with Toxic Heavy Metals, Plum and
12 Campbell/Sun-Maid also did not conduct heavy metal testing on Plum products prior to sale.
13 Plum only first conducted finished product testing in the wake of public reports that exposed
14 Plum baby food products as being contaminated with dangerous levels of heavy metals. Upon
15 information and belief, no rigorous heavy metal testing program on ingredients and finished
16 product was ever implemented and Plum and Campbell/Sun-Maid continued and continue to
17 sell baby food contaminated with elevated levels of heavy metals without first testing to ensure
18 their safety.

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

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

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

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

11 81. Internal documents within Sprout confirm that the companies were aware of
12 these issues, even made jokes about it, but took no action to take reasonable care to avoid harm
13 to infants until Congress blew the whistle on Sprout—and then, only after Sprout initially
14 refused to cooperate with a Congressional investigation.

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

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

24 84. The only efforts to police Toxic Heavy Metals in their Parent’s Choice baby food
25 involved generic specifications for lead and arsenic—there were no other specifications or
26 limits for other Toxic Heavy Metals—which for most baby food products resulted in there
27 being no limits. The following chart reflects Walmart’s Toxic Heavy Metal specifications prior
28 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>

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

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

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

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

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

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

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

10 EDF explained:

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

21 91. HBBF explained:

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

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

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

93. According to the World Health Organization (“WHO”), Toxic Heavy Metals, specifically lead, arsenic, mercury, and cadmium pose a “major public health concern” for

1 children. The Occupational Safety and Health Administration (“OSHA”) has warned that these
2 metals “may build up in biological systems and become a significant health hazard.” Indeed,
3 the Department of Health and Human Services’ Agency for Toxic Substances and Disease
4 Registry (“ATSDR”) ranks arsenic as number *one* among substances present in the environment
5 that pose the most significant potential threat to human health, followed by lead (second),
6 mercury (third), and cadmium (seventh).

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

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

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

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

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

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

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

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

1 disorders such as ADHD or autism spectrum disorder.”

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

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

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

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

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

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

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

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

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

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

27 109. No fewer than four large meta-analyses, conducted in four different continents
28 (North America, South America, Europe and Asia), and some employing a cross-sectional

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

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

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

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

28 ///

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

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

9 114. 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
11 cereal to impact early life neurodevelopment. Following analyses of the levels of arsenic
12 exposure from consumption of infant rice cereal, the authors concluded "that high consumers of
13 infant rice cereal (i.e., infants eating three servings per day) eating products currently on the
14 U.S. market would have a daily arsenic intake of 0.35-0.67 $\mu\text{g}/\text{kg bw}/\text{day}$...per the Tsuji et al.
15 (2015) lower-bound estimate for an RfD for the neurodevelopmental effects of arsenic (0.4
16 $\mu\text{g}/\text{kg bw}/\text{day}$), high consumers of infant rice cereal may also be at risk for this endpoint. Even
17 in average consumers of infant rice cereal (i.e., one serving per day), our estimates of arsenic
18 intakes (0.15 to 0.29 $\mu\text{g}/\text{kg bw}/\text{day}$) leave little room for exposures to arsenic from other
19 sources." Thus, consumption of Defendants' baby foods, including but not limited to infant rice
20 cereal and rice-based snack baby food products manufactured and sold by Defendants can
21 expose babies to levels of arsenic above that associated with neurodevelopmental harm in the
22 scientific literature.

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

28 116. Similarly, upon information and belief, Defendants were was aware of the

1 neurotoxic propensities of lead, arsenic, and mercury at low levels, but proceeded to
2 manufacture and sell Baby Foods containing arsenic and lead levels that, upon information and
3 belief, Defendants considered as capable of inflicting neurodevelopmental harm.

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

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

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

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

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

1 121. To be clear, the Defendants are able to manufacture baby foods that do not pose
2 such a dangerous risk to the health of infants and children by using alternative ingredients, not
3 adding certain pre-mix minerals and vitamins high in Toxic Heavy Metals or sampling their
4 ingredients from other sources. At the very least, Defendants were under a duty to warn
5 unsuspecting parents of the presence of Toxic Heavy Metals in their Baby Foods.

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

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

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

26 124. If Defendants specifically designed their baby food products to contain Toxic
27 Heavy Metals, meaning their presence was not the product of a manufacturing defect, then the
28 products were defective by design. Toxic Heavy Metals should not be present in foods that are

1 being consumed by infants and products should be designed to not have detectable levels of
2 toxic heavy metal in them. Such designs are easily accomplished, by only using ingredients that
3 contain non-detectable levels of Toxic Heavy Metals and by testing finished products, before
4 release, to ensure they do not contain Toxic Heavy Metals within them. This is possible
5 because there are examples of Defendants' finished products not containing detectable levels of
6 Toxic Heavy Metals—even if, for that same products, there are instances where they did. Thus,
7 Defendants were able to design baby food products to not contain detectable levels of toxic
8 heavy metals, and to the extent that each Defendants' design contemplated there being
9 detectable levels of Toxic Heavy Metals in baby food, the design, itself, was defective.

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

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

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

26 127. Defendants were fully aware of the safety risks of Contaminated Baby Foods,
27 particularly the dangerous potential of Toxic Heavy Metals on neurodevelopment in infants and
28 children. Nonetheless, Defendants deliberately crafted their label, marketing, and promotion to

1 mislead consumers. Indeed, Defendants repeatedly market their baby foods as safe for
2 consumption and go so far as claiming that they adhere to “the strictest standards in the world;”
3 and provide “baby’s food full of nutrition while meeting standards strict enough for tiny
4 tummies,” as well as other statements and representations that hold out their baby foods as safe
5 for consumption by infants. Indeed, each Defendant falsely reassured
6 parents/guardians/caregivers that their baby foods would foster healthy neurodevelopment when
7 consumed even though they knew their baby foods exposed infants’ developing brains to potent
8 neurotoxic heavy metals. In actual fact, as discussed above, Defendants routinely sold
9 Contaminated Baby Foods, regularly flouted their own internal limits of Toxic Heavy Metals
10 and failed to disclose to consumers that their products contained such dangerous contaminants.

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

21 **PLAINTIFF’S USE AND INJURY**

22 129. Plaintiff was diagnosed with ASD at approximately 3 years of age.

23 130. Plaintiff consumed Baby Food products manufactured and/or sold by the
24 Defendants.

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

28 132. Upon information and belief, as a direct and proximate result of consuming

1 Defendants' Baby Foods, Plaintiff was exposed to substantial quantities of Toxic Heavy Metals.

2 133. As a direct and proximate result of consuming Defendants' Baby Foods and the
3 exposure to the Toxic Heavy Metals therein – Plaintiff suffered brain injury which manifested
4 as ASD and related *sequalae*.

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

8 135. Had any Defendant warned Plaintiff's parents that Defendants' Baby Foods
9 could lead to exposure to Toxic Heavy Metals or, in turn, brain injury, Plaintiff would not have
10 consumed the Baby Foods.

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

15 **CAUSES OF ACTION**

16 **COUNT I: STRICT PRODUCTS LIABILITY – FAILURE TO WARN**

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

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

27 139. Defendants researched, tested, developed, designed, manufactured, labeled,
28 marketed, sold, inspected, distributed, and promoted, and otherwise released into the stream of

1 commerce their Contaminated Baby Foods, and in the course of same, directly advertised or
2 marketed the products to consumers and end users, including Plaintiff, and therefore had a duty
3 to warn about the presence of and risks associated with exposure to Toxic Heavy Metals from
4 the consumption of Contaminated Baby Foods.

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

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

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

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

1 graphically, to alert consumers to the presence of and health risks associated with exposure to
2 the Toxic Heavy Metals from Contaminated Baby Food consumption.

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

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

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

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

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

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

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

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

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

22 153. The Defendants' lack of adequate warnings and instructions accompanying their
23 Contaminated Baby Foods caused Plaintiff's injuries.

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

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

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

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

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

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

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

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

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

26 162. Nothing under federal law limited or restricted Defendants from taking action to

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

1 reduce or eliminate the Toxic Heavy Metals from being present in their baby foods.

2 163. This manufacturing defect caused Plaintiff to be exposed to Toxic Heavy Metals
3 through ingestion of the Contaminated Baby Foods which, in turn, caused neurodevelopmental
4 harm that manifested as ASD.

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

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

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

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

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

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

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

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

28 171. Defendants' Contaminated Baby Food products as researched, tested, developed,

1 designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by
2 Defendants were defective in design and formulation in that, when they were placed into the
3 stream of commerce, they were unreasonably dangerous and dangerous to an extent beyond that
4 which an ordinary consumer would contemplate.

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

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

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

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

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

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

28 3. Defendants, by design, did not sufficiently test, investigate, or study their

1 Contaminated Baby Food products;

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

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

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

11 176. Plaintiff consumed Defendants' Contaminated Baby Food products in an
12 intended or reasonably foreseeable manner without knowledge of their dangerous
13 characteristics.

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

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

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

26 180. The design defects in Defendants' Contaminated Baby Foods were substantial
27 factors in causing Plaintiff's injuries.

28 181. As a direct and proximate result of the Defendants' defective design of the

1 Contaminated Baby Foods, Plaintiff has been injured, sustained severe and permanent pain,
2 suffering, disability, impairment, loss of enjoyment of life, economic loss and damages
3 including, but not limited to medical expenses, lost income, and other damages.

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

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

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

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

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

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

1 the field.

2 187. At the time of manufacture, Defendants could have provided warnings regarding
3 the presence of and risks of exposure to Toxic Heavy Metals from consumption of
4 Contaminated Baby Foods because they knew or should have known exposure to Toxic Heavy
5 Metals from consumption of Contaminated Baby Foods was dangerous, harmful and injurious
6 when the Contaminated Baby Foods were consumed by Plaintiff in a reasonably foreseeable
7 manner.

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

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

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

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

28 192. The information that Defendants did provide or communicate failed to contain

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

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

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

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

25 196. Had Defendants provided adequate warnings and instructions and properly
26 disclosed and disseminated the risks associated with the presence of and exposure to Toxic
27 Heavy Metals in the Contaminated Baby Foods, Plaintiff could have avoided the risk of
28 developing injuries and could have obtained or used alternative products. However, as a result

1 of Defendants' concealment of the dangers posed by their Contaminated Baby Foods, Plaintiff
2 could not have averted their injuries.

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

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

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

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

18 **COUNT V: NEGLIGENCE – MANUFACTURING**

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

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

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

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

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

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

6 1. Failure to adequately inspect/test the Contaminated Baby Foods, and
7 their ingredients, during and after the manufacturing process;

8 2. Failure to implement procedures that would reduce or eliminate Toxic
9 Heavy Metals in baby foods;

10 3. Failure to investigate suppliers and ingredient sources to reduce and
11 eliminate the risk of ingredients containing Toxic Heavy Metals; and

12 4. Failure to avoid using ingredients free from, or which contain far less,
13 Toxic Heavy Metals to manufacture baby food.

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

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

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

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

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

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

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

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

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

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

11 215. The Defendants owed a duty to all reasonably foreseeable users to design a safe
12 product.

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

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

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

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

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

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

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

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

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

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

17 220. Defendants, by design, did not conduct adequate post-marketing surveillance of
18 their Contaminated Baby Foods.

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

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

28 223. A reasonable company under the same or similar circumstances would have

1 designed a safer product.

2 224. Plaintiff was harmed directly and proximately by the Defendants' failure to use
3 reasonable care in the design of their Contaminated Baby Foods. Such harm includes exposure
4 to Toxic Heavy Metals, which can cause or contribute to interference with neurodevelopment
5 that manifests as ASD and related *sequelae*.

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

9 226. The defects in Defendants' Contaminated Baby Foods were substantial factors in
10 causing Plaintiff's injuries.

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

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

18 **COUNT VII: GENERAL NEGLIGENCE**

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

21 230. Plaintiff pleads claims for negligence under all theories that may be actionable
22 under any applicable state laws.

23 231. Defendants owed Plaintiff a duty to act with reasonable care.

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

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

28 3. Defendants owed a duty because the risk of harm to Plaintiff was

1 embedded in, and an inherent component of, their negligent business practices.

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

4 232. Defendants breached their duty to Plaintiff.

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

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

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

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

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

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

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

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

27 8. Defendants did not sufficiently test, investigate, or study their
28 Contaminated Baby Foods and, specifically, the ability for those foods to expose babies to

1 Toxic Heavy Metals;

2 9. Defendants could have employed safer alternative designs and
3 formulations for Contaminated Baby Foods, such as ensuring the baby food did not have any
4 detectable level of Toxic Heavy Metal.

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

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

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

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

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

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

24 **JURY TRIAL DEMAND**

25 238. Plaintiff demands a trial by jury on all the triable issues within this pleading.

26 **PRAYER FOR RELIEF**

27 239. **WHEREFORE**, Plaintiff requests that the Court enter judgment in Plaintiff's
28 favor and against the Defendants for:

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

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Dated: January 30, 2026

Respectfully submitted,

/s/ Mark Schlein

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Attorneys for Plaintiff

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

SAFAA CLERMONT, on Behalf of E.E., A MINOR

(b) County of Residence of First Listed Plaintiff Polk County (EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number) WISNER BAUM, LLP; 11111 Santa Monica Blvd., Suite 1750; Los Angeles, CA 90025 Tel: (310) 207-3233

DEFENDANTS

Gerber Products Company, et al.

County of Residence of First Listed Defendant Arlington County (IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- 1 U.S. Government Plaintiff, 2 U.S. Government Defendant, 3 Federal Question (U.S. Government Not a Party), 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- Citizen of This State, Citizen of Another State, Citizen or Subject of a Foreign Country, PTF DEF, 1 1, 2 2, 3 3, 4 4, 5 5, 6 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

Click here for: Nature of Suit Code Descriptions.

Table with columns: CONTRACT, REAL PROPERTY, TORTS, CIVIL RIGHTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES. Includes various legal categories like Personal Injury, Real Property, Labor, etc.

V. ORIGIN (Place an "X" in One Box Only)

- 1 Original Proceeding, 2 Removed from State Court, 3 Remanded from Appellate Court, 4 Reinstated or Reopened, 5 Transferred from Another District, 6 Multidistrict Litigation - Transfer, 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity): 28 U.S. Code§ 1332(a) Brief description of cause: Diversity of Citizenship

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND \$ CHECK YES only if demanded in complaint: JURY DEMAND: [X] Yes [] No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE DOCKET NUMBER

DATE 1/30/2026 SIGNATURE OF ATTORNEY OF RECORD /s/ Mark Schlein

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

- I.(a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
- (b) County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
- (c) Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".
- II. Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
 United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here. United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
 Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
 Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)
- III. Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: [Nature of Suit Code Descriptions](#).
- V. Origin.** Place an "X" in one of the seven boxes.
 Original Proceedings. (1) Cases which originate in the United States district courts.
 Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
 Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
 Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
 Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
 Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
 Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.
- VI. Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service.
- VII. Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
 Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
 Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.
- VIII. Related Cases.** This section of the JS 44 is used to reference related cases, if any. If there are related cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.