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**UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA**

N.C., a minor, represented by his mother and
Guardian ad Litem, Judith Chavez,

Plaintiff,

v.

Gerber Products Company; and DOES 1
through 10 inclusive,

Defendants.

CASE NO: 5:24-cv-00612

COMPLAINT FOR DAMAGES

DEMAND FOR JURY TRIAL

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INTRODUCTION

1
2 1. This case involves manufacturers/sellers—including Defendant Gerber Food
3 Company—that *knowingly* sold baby food products (“Baby Foods”) which contain dangerous levels of
4 toxic heavy metals—lead, arsenic, and mercury (collectively “Toxic Heavy Metals”), which are known
5 to be severe neurotoxins—and how such toxic exposures substantially contributed to Plaintiff
6 developing lifelong brain injury. Plaintiff is a child who lives with debilitating brain injury, namely in
7 the form of the neurodevelopmental disorder autism spectrum disorder (“ASD”) and related *sequelae*
8 because, as an infant, he consumed poisonous Baby Foods manufactured and/or sold by these
9 Defendants. This case seeks to hold the Defendants accountable for their reprehensible conduct and
10 ensure they are punished for permanently affecting Plaintiff’s ability to live a fulfilling life.

11 2. That Defendants’ Baby Foods are laced with staggering amounts of Toxic Heavy Metals
12 recently made headlines following research and a Congressional investigation. In February 2021, the
13 U.S. House of Representatives’ Subcommittee on Economic and Consumer Policy, Committee on
14 Oversight and Reform released a report containing shocking details of Defendants’ tainted Baby Foods
15 based on the submission of internal test results and company documents. Specifically, the
16 Subcommittee found that Defendants sell Baby Foods containing levels of heavy metals ranging from
17 tens to hundreds of parts per billion (“ppb”),¹ far eclipsing domestic and international regulatory
18 standards. With a chilling note the Subcommittee concluded that “[m]anufacturers *knowingly* sell these
19 products to unsuspecting parents, in spite of internal company standards and test results, and without
20 any warning labeling whatsoever.”² (emphasis added). Indeed, following the Congressional findings
21 and subsequent public uproar, Defendant Beech-Nut recalled one of its baby food product lines from
22

23 ¹ Ppb (or ppbm) is used to measure the concentration of a contaminant in soils, sediments, and water.
24 1 ppb equals 1 µg (microgram) of substance per kg of solid (µg/kg). For the average baby weighing
25 approximately 3kg, the quantities of Toxic Heavy Metals found in Defendants’ Baby Foods, as
explained below, pose significant health risks.

26 ² Ex. 1, Staff Report, Subcommittee on Economic and Consumer Policy Committee on Oversight and
27 Reform U.S. House of Representatives, *Baby Foods Are Tainted with Dangerous Levels of*
Arsenic, Lead, Cadmium, and Mercury (Feb. 4, 2021) (“Subcommittee Report”) at 59, available at:
28 <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-02-04%20ECP%20Baby%20Food%20Staff%20Report.pdf>.

1 the market, citing dangerous levels of arsenic in its single grain rice cereal, and exited the rice cereal
2 market altogether.³

3 3. The high levels of Toxic Heavy Metals found in Defendants' Baby Foods are, in part, a
4 function of the ingredients used by Defendants to manufacture their Baby Foods, the setting of
5 dangerously inflated internal limits which Defendants willingly flouted, disregard of regulatory
6 standards, and corporate policies which failed to test finished products before market distribution,
7 purchase by unknowing parents, and consumption by vulnerable infants.

8 4. Defendants' malicious recklessness and callous disregard for human life has wreaked
9 havoc on the health of countless vulnerable children, all so that Defendants could maximize profits
10 while deliberately misleading parents regarding the safety of their Baby Foods. Accordingly, this
11 lawsuit will not only ensure that Plaintiff is duly compensated for his tragic injuries and Defendants
12 punished, but that future generations are protected from the poisonous products that Defendants pander
13 as "food".

14 **PARTIES**

15 **I. Plaintiff**

16 5. Plaintiff is a citizen of California and no other state.

17 **II. Defendants**

18 6. Defendant Gerber Products Company ("Gerber") is a citizen of Michigan with its
19 principal place of business located at 445 State Street, Fremont, MI 49413-0001. Gerber sells Baby
20 Foods under the brand name Gerber. Gerber organizes its products into broad categories of "formula",
21 "baby cereal", "baby food", "snacks", "meals & sides" "beverages" and "organic". At all relevant
22 times, Gerber has conducted business and derived substantial revenue from its manufacturing,
23 advertising, distributing, selling, and marketing of Baby Foods within this judicial district.

24 7. The true names and/or capacities, whether individual, corporate, partnership, associate,
25

26 ³ FDA, *Beech-Nut Nutrition Company Issues a Voluntary Recall of One Lot of Beech-Nut Single*
27 *Grain Rice Cereal and Also Decides to Exit the Rice Cereal Segment*, available at:
28 <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/beechnut-nutrition-company-issues-voluntary-recall-one-lot-beech-nut-single-grain-rice-cereal-and>

1 governmental, or otherwise, of Defendants DOES 1 through 100, inclusive, and each of them, are
2 unknown to Plaintiff at this time, who therefore sue said Defendants by such fictitious names. Plaintiff
3 is informed and believe, and thereon allege, that each Defendant designated herein as a DOE caused
4 injuries and damages proximately thereby to Plaintiff as hereinafter alleged; and that each DOE
5 Defendant is liable to the Plaintiff for the acts and omissions alleged herein below, and the resulting
6 injuries to Plaintiff, and damages sustained by Plaintiff. Plaintiff will amend this Complaint to allege
7 the true names and capacities of said DOE Defendants when that same is ascertained. At all relevant
8 times, Defendants and DOES 1 through 100, inclusive, and each of them, expected or should have
9 expected that their acts would have consequences within the United States of America including the
10 State of California and including Los Angeles County, said Defendants derived and derive substantial
11 revenue therefrom.

12 **JURISDICTION AND VENUE**

13 8. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332. There is
14 complete diversity of citizenship between the parties. In addition, Plaintiff seeks damages in excess of
15 \$75,000, exclusive of interest and costs.

16 9. This Court has personal jurisdiction over Defendants insofar as Defendants are
17 authorized and licensed to conduct business in the State of California, maintain and carry on systematic
18 and continuous contacts in this judicial district, regularly transact business within this judicial district,
19 and regularly avail themselves of the benefits of this judicial district.

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

24 11. Venue is proper before this Court pursuant to 28 U.S.C. § 1391 because a substantial
25 part of the events or omissions giving rise to the claim occurred in this judicial district.

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FACTUAL ALLEGATIONS

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

12. In October 2019, an alliance of nonprofit organizations, scientists and donors named “Happy Babies Bright Futures” (“HBBF”), dedicated to designing and implementing “outcomes-based programs to measurably reduce babies’ exposures to toxic chemicals”⁴, published a report investigating the presence of Toxic Heavy Metals in baby foods.⁵ The HBBF Report tested 168 different baby foods sold on the U.S. market and concluded that “[n]inety-five percent of baby foods tested were contaminated with one or more of four toxic heavy metals—arsenic, lead, cadmium and mercury. All but nine of 168 baby foods contained at least one metal; most contained more than one.”⁶ Specifically, the HBBF report identified “puffs and other snacks made with rice flour”, “[t]eething biscuits and rice rusks”, “infant rice cereal”, “apple, pear, grape and other fruit juices”, and “carrots and sweet potatoes” manufactured by the Defendant Baby Food Companies as particularly high in Toxic Heavy Metals.⁷

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

⁴ <https://www.hbbf.org/solutions>.

⁵ Healthy Babies Bright Futures, *What’s in My Baby’s Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies’ IQ, Including Arsenic and Lead* (Oct. 2019) (“HBBF Report”), available at: www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf).

⁶ *Id.* at 6.

⁷ *Id.* at 10-11

⁸ *Id.* at 6.

⁹ *Id.* at 6.

1 foods.”¹⁰ The study detected lead in 37% of samples.¹¹ This was consistent with findings by
2 researchers examining baby food products in other parts of the world.

3 **II. Congressional Investigation Finds Substantial Presence of Heavy Metals in Baby Foods** 4 **Sparking National Outrage**

5 14. On February 4, 2021, the U.S. House of Representatives’ Subcommittee on Economic
6 and Consumer Policy, Committee on Oversight and Reform, published a report detailing its findings
7 that Toxic Heavy Metals—including lead, arsenic, and mercury—were present in “significant levels”
8 in numerous commercial baby food products.¹² Four companies—Hain, Gerber, Nurture, and Beech-
9 Nut—produced internal testing policies, test results for ingredients and finished products, and
10 documentation about what the companies did with ingredients and/or finished products that exceeded
11 their internal testing limits. Three companies—Plum, Walmart, and Sprout—refused to cooperate.¹³

12 15. The Subcommittee reported that the data submitted by the companies unequivocally
13 revealed that a substantial number of Defendants’ finished products and/or ingredients used to
14 manufacture the Baby Foods are tainted with significant levels of Toxic Heavy Metals, namely lead,
15 arsenic, and mercury.¹⁴ And, where the Defendants did set internal limits for the amount of metals
16 they allowed in their foods, Defendants routinely flouted their own limits and sold foods that
17 consistently tested above their limits.

18 16. **Gerber** used high-arsenic ingredients, using 67 batches of rice flour that had tested over
19 90 ppb inorganic arsenic. Gerber used ingredients that tested as high as 48 ppb lead; and used many
20 ingredients containing over 20 ppb lead. Gerber rarely tests for mercury in its baby foods. In the
21 September 2021 follow-up Congressional report, it was revealed that Gerber’s rice cereal tested up to
22 116 ppb inorganic arsenic, and its average rice cereal product contained 87.43 ppb inorganic arsenic,
23

24
25 ¹⁰ Gardener, et al., *Lead and cadmium contamination in a large sample of United States infant*
26 *formulas and baby foods*, 651 SCI. TOTAL ENVIRON. 1, 822-827 (2019), available at:
<https://www.sciencedirect.com/science/article/abs/pii/S0048969718334442?via%3Dihub>.

27 ¹¹ *Id.*

28 ¹² *See generally* Subcommittee Rpt.

¹³ Subcommittee Rpt. at 2.

¹⁴ *Id.* at 2-3.

1 which is even higher than the amount contained in Beech-Nut’s average rice cereal product. While
2 Beech-Nut recalled some of its products and completely discontinued sales of its rice cereal, Gerber
3 has taken no such actions to protect children.

4 17. Gerber’s Baby Foods are also contaminated with elevated levels of lead. Gerber used
5 ingredients that tested as high as 48 ppb lead; and used many ingredients containing over 20 ppb lead.
6 Furthermore, upon information and belief, Gerber has sold Baby Food products testing at and/or above
7 50 ppb of lead. Indeed, upon information and belief, Gerber has historically permitted as much as 150
8 ppb of lead into their Baby Food products. Although Gerber was fully aware that it was very feasible
9 – with achievability rate of 90% - to source lower-lead ingredients, the Gerber proceeded to use high-
10 lead ingredients in its foods. Gerber rarely tests for mercury in its baby foods.¹⁵ This, notwithstanding
11 the fact that mercury is known to contaminate ingredients such as rice and poses a severe risk to babies’
12 brain development.

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

23 19. Moreover, compounding these troubling findings, the Defendants set internal limits for
24 the presence of Toxic Heavy Metals in their foods that were, themselves, dangerously high and then
25 routinely failed to abide by those inadequate standards, as discussed below. For example, the
26 Subcommittee found that Hain (Earth’s Best Organic) set an internal standard of 200 ppb for arsenic

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28 ¹⁵ *Id.* at 2-4.

1 and lead in some of its ingredients. But Hain routinely exceeded its internal policies, using ingredients
2 containing 353 ppb lead and 309 ppb arsenic. Hain justified these deviations based on “theoretical
3 calculations,” even after Hain admitted to FDA that its testing *underestimated* final product toxic heavy
4 metal levels.¹⁶ And, upon information and belief, Gerber has historically only tested certain ingredients
5 of its Baby Food products and rarely tested the finished products consumed by babies. Upon
6 information and belief, it was not until recently that Gerber started to implement finished product
7 testing on its infant rice cereals, but none of its other Baby Food products. And, Gerber regularly
8 flouted their own internal metal limits. Upon information and belief, regulatory testing found that a
9 portion of Gerber’s and Nestle’s infant rice cereals tested above 100 ppb. Such a metal level presents
10 a risk to the neurodevelopment of babies consuming the products. Notwithstanding, the products were
11 never recalled, and Gerber continued to market these products to vulnerable babies.

12 20. As found by the Subcommittee, the Defendants have willfully sold—and continue to
13 sell—contaminated Baby Foods notwithstanding their full awareness of these unacceptably high levels
14 of Toxic Heavy Metals in their products. In August 2019, Hain held a closed-door meeting with the
15 FDA during which Hain delivered a presentation to the agency acknowledging the Toxic Heavy Metal
16 problem in its Baby Food.¹⁷ In the PowerPoint slides presented during the meeting—only made public
17 by the Subcommittee—Hain confirmed that some of the ingredients in its Baby Food contain as much
18 as between 108 to 129 ppb of arsenic, specifically noting “[p]reliminary investigation indicates
19 Vitamin/Mineral Pre-Mix may be a major contributing factor.”¹⁸

20 **III. Dangers of Toxic Heavy Metals to Babies and Children**

21 21. According to the World Health Organization (“WHO”), Toxic Heavy Metals,
22 specifically lead and arsenic pose a “major public health concern” for children.¹⁹ The Occupational
23

24 ¹⁶ *Id.* at 4-5.

25 ¹⁷ Hain, *PowerPoint Presentation to Food and Drug Administration: FDA Testing Result*
26 *Investigation* (Aug. 1, 2019) (“2019 Hain & FDA Meeting”), available at:
<https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2.pdf>.

27 ¹⁸ *Id.* at *9.

28 ¹⁹ World Health Organization, *Children’s Health and the Environment WHO training Package for the*
Health Sector (October 2011), available at: https://www.who.int/ceh/capacity/heavy_metals.pdf.

1 Safety and Health Administration (“OSHA”) has warned that these metals “may build up in biological
2 systems and become a significant health hazard.”²⁰ Indeed, the Department of Health and Human
3 Services’ Agency for Toxic Substances and Disease Registry (“ATSDR”) ranks arsenic as number *one*
4 among substances present in the environment that pose the most significant potential threat to human
5 health, followed by lead (second), and mercury (third).

6 22. The threat presented by Toxic Heavy Metals to children’s health is widely shared by the
7 global scientific community. For example, the FDA has set an Interim Reference Level (“IRL”) of 2.2
8 micrograms/day for lead exposure through baby food products.²¹ That is the amount of lead exposure
9 above which the agency considers associated with adverse neurological effects in babies. None of the
10 Defendant Baby Food Manufacturers have ever conducted any tests or analyses to determine whether
11 exposure to lead from their baby food products would result in children having blood lead amounts of
12 2.2 micrograms/day. The FDA, in its guidance documents for inorganic arsenic and lead in baby food
13 products has repeatedly acknowledged the dangers of heavy metals to the neurodevelopment of infants.

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

25 23. As one recent study observed, “[t]he implications of heavy metals with regards to
26 children’s health have been noted to be more severe compared to adults. The elements’ harmful
27 consequences on children health include mental retardation, neurocognitive disorders, behavioral
28 disorders, respiratory problems, cancer and cardiovascular diseases. Much attention should be given

26 ²⁰ OSHA, *Toxic Metals*, available at: <https://www.osha.gov/toxic-metals>.

27 ²¹ FDA (January 2023) *Action Levels for Lead in Food Intended for Babies and Young Children:*
28 *Draft Guidance For Industry*, available at: <https://www.fda.gov/media/164684/download>.

²² *Id.*

1 to heavy metals because of their high toxicity potential, widespread use, and prevalence.”²³ Children
2 and, even more so, babies have higher exposure to metals compared to adults because they consume
3 more food in relation to their body weight and absorb metals more readily than adults by 40 to 90%.²⁴
4 And, the mechanisms needed to metabolize and eliminate heavy metals are comparatively undeveloped
5 in childhood, with babies having weaker detoxifying mechanisms and poorer immune systems than
6 adults.²⁵ For example, liver pathways that in adulthood metabolize absorbed arsenic do not mature
7 until mid-childhood; un-excreted arsenic thus continues to circulate and is deposited in other organs.²⁶
8 According to Linda McCauley, Dean of the Nell Hodgson Woodruff School of Nursing at Emory
9 University, who studies environmental health effects, “[n]o level of exposure to these [heavy] metals
10 has been shown to be safe in vulnerable infants.”²⁷ Thus, “the major windows of developmental
11 vulnerability occur during infancy and early childhood due to continuing brain development after
12 birth.”²⁸ In short, even small amounts of exposure to Toxic Heavy Metals can have devastating health
13 outcomes for babies and children.

14
15 24. Notably, none of the Defendants ever conducted any kind of risk assessments or
16 analyses to determine whether exposure to their baby food products exposed children to lead amounts
17 known to harm neurodevelopment. On information and belief, exposure to Defendants’ Baby Food
18 products exposed Plaintiff to heavy metal concentrations known to result in brain injury.

19 25. Indeed, upon and information and belief, Gerber (through research conducted by its
20

21 ²³ Osman, et al., *Exposure routes and health effects of heavy metals on children*, 32 BIOMETALS 563–
22 573 (2019), available at: <https://link.springer.com/article/10.1007%2Fs10534-019-00193-5#citeas>.

23 ²⁴ Stein, et al., *In harm’s way: toxic threats to child development*, 23 J DEV BEHAV PEDIATR.1 S13–
24 S22 (2002).

25 ²⁵ Gorini, et al., *The Role of Heavy Metal Pollution in Neurobehavioral Disorders: a Focus on Autism*
26 1 REV. J. AUTISM DEV. DISORD. 1, 354–372 (2014), available at:
27 <https://link.springer.com/article/10.1007/s40489-014-0028-3>.

28 ²⁶ Del Rio, et al., *A comparison of arsenic exposure in young children and home water arsenic in two
rural West Texas communities* 17 BMC PUBLIC HEALTH 850 1-13 (2017), available at:
<https://bmcpublihealth.biomedcentral.com/articles/10.1186/s12889-017-4808-4>.

²⁷ Roni Caryn Rabin, *Some Baby Food May Contain Toxic Metals, U.S. Reports* (NY TIMES, Feb 4,
2021), available at: <https://www.nytimes.com/2021/02/04/health/baby-food-metals-arsenic.html>

²⁸ Gorini, et al. *supra*.

1 parent company's own private research group Nestle Research Center in Switzerland) has been aware
2 for over two decades that low levels of arsenic can harm children's neurodevelopment. Indeed, in its
3 2019 letter to Congress, Nestle bragged that it has access to a network of 4,800 experts, including
4 scientists and toxicologists. Notwithstanding this, neither Gerber nor Nestle conducted any kind of
5 risk assessments or analyses to determine whether exposure to their baby food products exposed
6 children to lead amounts known to harm neurodevelopment until concerns regarding contaminated
7 baby foods entered widespread public discourse in recent years.

8 **A. Exposure to Toxic Heavy Metals Has Been Consistently Associated with Brain**
9 **Injury, i.e., Autism and ADHD in Pediatric Populations**

10 26. It is well-known that exposure to heavy metals in early life can cause brain injury at low
11 levels of exposure. And one of the ways in which such brain injury can present in a child is in the form
12 of the neurodevelopmental disorders ASD and ADHD. As the U.S. Centers for Disease Control
13 observed in its 2020 Toxicological Profile for Lead, at just ≤ 10 $\mu\text{g}/\text{dL}$: "The following neurobehavioral
14 effects in children have been associated with [lead]: "Altered mood and behaviors that may contribute
15 to learning deficits, including *attention deficits*, *hyperactivity*, *autistic behaviors*, conduct disorders,
16 and delinquency."²⁹ (emphasis added). Likewise, the NIH states: "prenatal and early childhood
17 exposure to heavy metals...may be linked to autism spectrum disorder."³⁰

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

21 28. For example, four meta-analyses published in 2014, 2017, 2019 and 2020, respectively,
22 all observed a consistent association between exposure to arsenic and mercury and ASD in children;
23 with the authors in all three studies recommending – based on the data – that exposure to such metals
24 in children be reduced as much as possible, and one of the study authors specifically concluding that
25

26 _____
27 ²⁹ ATSDR (2020) *Toxicological Profile for Lead*, available at:
28 <https://www.atsdr.cdc.gov/toxprofiles/tp13.pdf>.

³⁰ NIH, ASD & the Environment.

1 “Results of the current meta-analysis revealed that mercury is an important causal factor in the etiology
2 of ASD.”³¹

3 29. In a recent 2017 NIH-funded prospective observational study, the authors examined the
4 risk of ASD outcome in twins based on their respective body burden of lead. The study concluded in
5 no uncertain terms that “prenatal and early childhood disruption (excess or deficiency) of multiple
6 metals during critical developmental windows is associated with ASD, and suggests a role for
7 elemental dysregulation in the etiology of ASD.”³²

8 30. Similarly, a large, prospective study from 2016 in Korean school children observed that
9 low levels of lead exposure in early life are associated with autism, the authors specifically concluding:
10 “even low blood lead concentrations...are associated with more autistic behaviors..., underscoring the
11 need for continued efforts to reduce lead exposure.”³³

12 31. Furthermore, repeated associations between early life metal exposure and ASD have
13 also been observed during the pre-natal timeframe, lending further strength to the findings of post-natal
14 studies. For example, in a 2021 study by Skogheim and colleagues, the authors prospectively assessed
15 the relationship between pre-natal metal exposure in various biomarkers and autism risk. The study
16 concluded that “[r]esults from the present study show several associations between levels of metals and
17 elements during gestation and ASD and ADHD in children. The most notable ones involved
18 arsenic...mercury...and lead. Our results suggest that even population levels of these compounds may
19

20 ³¹ Jafari, et al., *The association between mercury levels and autism spectrum disorders: A systematic*
21 *review and meta-analysis* 44 J. TRACE. ELEMEN. IN MED. & BIOL. 289-297 (2017); Wang, et al.,
22 *Exposure to Inorganic Arsenic and Lead and Autism Spectrum Disorder in Children: A Systematic*
23 *Review and Meta-Analysis*, 21 CHEM RES. TOXICOL. 32, 1904-1919 (2019), available at:
24 <https://pubmed.ncbi.nlm.nih.gov/31549506/>; Sulaiman, et al., *Exposure to Aluminum, Cadmium, and*
25 *Mercury and Autism Spectrum Disorder in Children: A Systematic Review and Meta-Analysis*, 33
26 Chem. Res. Toxicol. 11, 2699-2718 (2020), available at: <https://pubmed.ncbi.nlm.nih.gov/32990432/>;
27 Yoshimasu, et al., *A meta-analysis of the evidence on the impact of prenatal and early infancy*
28 *exposures to mercury on autism and attention deficit/hyperactivity disorder in the childhood*, 44
NEURO TOXICOL. 121-131 (2014), available at: <https://pubmed.ncbi.nlm.nih.gov/24952233/>.

³² Arora, et al., *Fetal and postnatal metal dysregulation in autism* NATURE COMM. 1-10 (2017),
available at: <https://www.nature.com/articles/ncomms15493>.

³³ Kim, et al., *Low-Level lead Exposure and Autistic Behaviors in School-Age Children*, 53
NEUROTOXICOLOGY 193-200 (2016).

1 have negative impacts on neurodevelopment.”³⁴ Similarly, in a study by the research group assessing
 2 the New Hampshire Birth Cohort, the authors evaluated the neurotoxic effects of heavy metals during
 3 various stages of pregnancy and concluded: “Our results support the hypothesis that exposure to...As
 4 in mid to late pregnancy may be neurodevelopmentally harmful.”³⁵

5 32. Moreover, such results have been replicated in studies throughout the world, including
 6 China, Korea, the U.S., Europe, and Egypt, implicating arsenic, mercury, and lead in pediatric
 7 diagnoses of autism and autistic behaviors, with a 2018 Chinese study concluding: “[t]he results of this
 8 study are consistent with numerous previous studies, supporting an important role for heavy metal
 9 exposure, particularly mercury, in the etiology of ASD.”³⁶ Indeed, a 2015 Egyptian study noted
 10 “[e]nvironmental exposure to these toxic heavy metals, *at key times in development*, may play a causal
 11 role in autism.” (emphasis added).³⁷

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

14 34. No fewer than four large meta-analyses, conducted in four different continents (North
 15 America, South America, Europe and Asia), and some employing a cross-sectional design, have
 16

17 ³⁴ Skogheim, et al. *Metal and essential element concentrations during pregnancy and associations*
 18 *with autism spectrum disorder and attention-deficit/hyperactivity disorder in children* 152 1-14
 19 (2021).

20 ³⁵ Doherty, et al., *Periconceptional and prenatal exposure to metal mixtures in relation to behavioral*
 21 *development at 3 years of age* 4 ENVIRON. EPIDEMIOLOG. (2020).

22 ³⁶ Li, et al., *Blood Mercury, Arsenic, Cadmium, and Lead in Children with Autism Spectrum*
 23 *Disorder*, 181 BIOL TRACE ELEM RES 31-37 (2018), available at:

24 <https://pubmed.ncbi.nlm.nih.gov/28480499/>; Ryu, et al., *Associations of prenatal and early childhood*
 25 *mercury exposure with autistic behaviors at 5 years of age: The Mothers and Children's*

26 *Environmental Health (MOCEH) study*, 15 SCI. TOTAL ENVIRON. 251-257 (2017), available at:

27 <https://www.sciencedirect.com/science/article/abs/pii/S0048969717316479>; Dickerson, et al., *Autism*
 28 *spectrum disorder prevalence and associations with air concentrations of lead, mercury, and arsenic*,

188 ENVIRON MONIT. ASSESS. 407 (2016); Mohamed, et al., *Assessment of Hair Aluminum, Lead, and*
 29 *Mercury in a Sample of Autistic Egyptian Children: Environmental Risk Factors of Heavy Metals in*

30 *Autism* BEHAV. NEUROL. (2015), available at: <https://pubmed.ncbi.nlm.nih.gov/26508811/>; Adams, et al., *Toxicological Status of Children with Autism vs. Neurotypical Children and the Association with*

31 *Autism Severity*, 151 BIOL. TRACE ELEM. RES 171-180 (2013), available at:

32 <https://pubmed.ncbi.nlm.nih.gov/23192845/>.

33 ³⁷ Mohamed, et al.

1 observed a consistent associated association between various metals and ADHD in children.³⁸ Indeed,
 2 the authors of the meta-analysis from Spain noted that “the evidence from the studies allowed us to
 3 establish that there is an association between lead and ADHD and that even *low levels of lead raise the*
 4 *risk.*” (emphasis added).³⁹

5 35. The findings from the meta-analyses have been replicated in several Chinese studies
 6 from 2006, 2014 and 2018, respectively.⁴⁰ Notably, the authors of the 2014 Chinese study observed
 7 that “[e]xposure to lead even at low levels correlates with attention-deficit/hyperactivity disorder
 8 (ADHD). However, lead-contaminated environments are often *contaminated with other heavy metals*
 9 *that could exacerbate lead-induced ADHD.*” (emphasis added).⁴¹ This is particularly relevant—and
 10 disturbing—as children who consumed Defendants’ Baby Food were repeatedly exposed to a cocktail
 11 of Toxic Heavy Metals that, synergistically, further increased their risk of developing ADHD.

12 36. Moreover, studies have observed a dose-response relationship between exposure to
 13 Toxic Heavy Metals and ADHD, as demonstrated by the 2016 Spanish study Donzelli, *et al.* discussed
 14 *supra*. Another 2016 cross-sectional study from Spain was conducted on 261 children aged 6-9 to
 15

16 ³⁸ Muñoz, et al., *Attention deficit hyperactivity disorder and its association with heavy metals in*
 17 *children from northern Chile*, 226 INT. J. HYG. ENVIRON. HEALTH (2020), available at:
 18 <https://europepmc.org/article/med/32106053>; Yoshimasu, et al., *supra*; Donzelli, et al., *The*
 19 *Association between Lead and Attention-Deficit/Hyperactivity Disorder: A Systematic Review*, 16
 20 INT. J. ENVIRON. RES. PUBLIC HEALTH 382, 1-14 (2019), available at:
 21 <https://pubmed.ncbi.nlm.nih.gov/30700018/>; Goodland, et al., *Lead and Attention-*
 22 *Deficit/Hyperactivity Disorder (ADHD) symptoms: A meta-analysis*, 33 CLIN. PSYCHOL. REV. 3, 417-
 23 242 (2013), available at: <https://pubmed.ncbi.nlm.nih.gov/23419800/>.

24 ³⁹ Donzelli et al, *supra*.

25 ⁴⁰ Lee, et al., *Heavy Metals’ Effect on Susceptibility to Attention-Deficit/Hyperactivity Disorder:*
 26 *Implication of Lead, Cadmium, and Antimony*, 15 INT. J. ENVIRON. RES. PUBLIC HEALTH. 6, 1-2
 27 (2018), available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6025252/>; Liu, et al., *S100β in*
 28 *heavy metal-related child attention-deficit hyperactivity disorder in an informal e-waste recycling*
area, 45 NEURO TOXICOL. 185-191 (2014), available at:
<https://www.sciencedirect.com/science/article/abs/pii/S0161813X14001831>; Wong, V.C.N,
Attention-Deficit Hyperactivity Disorder and Blood Mercury Level: a Case-Control Study in Chinese
Children, 37 NEURO PEDIATRICS 4, 234-40 (2006), available at:
[https://www.researchgate.net/publication/6623327_Attention-](https://www.researchgate.net/publication/6623327_Attention-Deficit_Hyperactivity_Disorder_and_Blood_Mercury_Level_a_Case-Control_Study_in_Chinese_Children)
[Deficit_Hyperactivity_Disorder_and_Blood_Mercury_Level_a_Case-](https://www.researchgate.net/publication/6623327_Attention-Deficit_Hyperactivity_Disorder_and_Blood_Mercury_Level_a_Case-Control_Study_in_Chinese_Children)
[Control_Study_in_Chinese_Children.](https://www.researchgate.net/publication/6623327_Attention-Deficit_Hyperactivity_Disorder_and_Blood_Mercury_Level_a_Case-Control_Study_in_Chinese_Children)

⁴¹ Liu, et al. *supra*

1 examine the association between exposure to arsenic and ADHD.⁴² After adjusting for potential
2 confounders, the authors observed a dose-response relationship between urine arsenic levels and
3 inattention and impulsivity scores, concluding that “[urine arsenic] levels were associated with
4 impaired attention/cognitive function, *even at levels considered safe*. These results provide additional
5 evidence that postnatal arsenic exposure impairs neurological function in children.”⁴³ (emphasis
6 added).

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

13 **IV. Defendants Knowingly Sold Baby Foods Containing Dangerous Levels of Toxic Heavy** 14 **Metals and Knew or Should Have Known of the Risks of Such Exposures in Children**

15 38. During the time that Defendants manufactured and sold Baby Foods in the United
16 States, the weight of evidence showed that Defendants’ Baby Foods exposed babies and children to
17 unsafe levels of Toxic Heavy Metals. Defendants failed to disclose this risk to consumers through any
18 means.

19 39. As discussed above, both independent testing, the Defendants’ internal evaluations of
20 their Baby Foods, and the Defendants’ representations and disclosures to the Subcommittee and FDA
21 reveal the presence of substantial amounts of Toxic Heavy Metals in Defendants’ products. As such,
22 Defendants knew or should have known that their Baby Foods contain dangerous of Toxic Heavy
23 Metals.

24 40. Indeed, independent testing performed in early 2019 demonstrated elevated amounts of
25
26

27 ⁴² Rodriguez-Barranco, et al., *Postnatal arsenic exposure and attention impairment in school*
28 *children*, 74 CORTEX 370-382 (2016).

⁴³ *Id.*

1 such Toxic Heavy Metals in Baby Food products on the U.S. market,⁴⁴ and the HBBF Report further
2 confirmed such contamination of Defendants' Baby Foods.⁴⁵ And, as the Subcommittee found, the
3 Defendants continued to sell their Baby Foods even after testing of both ingredients and finished
4 products revealed the presence of substantial amounts of Toxic Heavy Metals.⁴⁶

5 41. Moreover, the scientific literature on the dangers of Toxic Heavy Metals—particularly
6 as it relates to adverse effects on the neurodevelopment of children—have been well known for
7 decades. Defendants, as manufacturers and retailers of Baby Foods, are held to the standard of experts
8 responsible for keeping abreast of the latest scientific developments related to the dangers of
9 contaminants in their products. Furthermore, as alleged in more detail below, the Retailer Defendant is
10 strictly liable for selling the Baby Foods which caused Plaintiff's harm. Defendants failed to take action
11 in protecting vulnerable children from exposure to the Toxic Heavy Metals in their foods and, thus,
12 subjected them to the risk of brain injury which can manifest as neurodevelopmental disorders such as
13 ASD, ADHD, and related *sequelae*.

14 42. To be clear, the Defendants are able to manufacture Baby Foods that do not pose such
15 a dangerous risk to the health of infants and children by using alternative ingredients, not adding certain
16 pre-mix minerals and vitamins high in Toxic Heavy Metals, or sampling their ingredients from other
17 sources, as specifically acknowledged by Hain in its August 2019 presentation to the FDA: "Explore
18 alternatives for Brown Rice ingredient to reduce risk."⁴⁷ At the very least, Defendants were under a
19 duty to warn unsuspecting parents of the presence of Toxic Heavy Metals in their Baby Foods.
20 However, Defendants took no action, continued to sell their products with full knowledge of the risks
21 posed by their Baby Foods, and misled consumers regarding the safety of their products, all to the harm
22 of children.

23 **V. Exemplary / Punitive Damages Allegations**

24 43. Defendants' conduct as alleged herein was done with reckless disregard for human life,
25

26 ⁴⁴ See Gardener, et al., *supra*.

27 ⁴⁵ See HBBF Report, *supra*.

28 ⁴⁶ See, e.g., Subcommittee Report at 13-14.

⁴⁷ 2019 Hain & FDA Meeting at *10.

1 oppression, and malice. Defendants’ conduct is particularly reprehensible given that their toxic foods
2 were directed at vulnerable babies—a population group far more susceptible than adults to the
3 neurotoxic dangers of heavy metals.

4 44. Defendants were fully aware of the safety risks of Baby Foods, particularly the
5 dangerous potential of their Baby Foods given the high content of Toxic Heavy Metals that have all
6 been associated with brain injury in children. Nonetheless, Defendants deliberately crafted their label,
7 marketing, and promotion to mislead consumers. Indeed, Defendants repeatedly market their Baby
8 Foods as safe for consumption and go so far as claiming that they adhere to “the strictest standards in
9 the world”; and provide “baby’s food full of nutrition while meeting standards strict enough for tiny
10 tummies” as well as other statements and representations that hold out their Baby Foods as safe for
11 consumption by infants. In actual fact, as discussed above, Defendants routinely sold Baby Foods
12 containing astronomical amounts of Toxic Heavy Metals, regularly flouted their own internal limits of
13 Toxic Heavy Metals in Baby Foods and failed to disclose to consumers that their products contained
14 such dangerous contaminants.

15 45. This was not done by accident or through some justifiable negligence. Rather,
16 Defendants knew they could profit by convincing consumers that their Baby Foods were harmless to
17 humans, and that full disclosure of the true risks of the Toxic Heavy Metals present in the Baby Foods
18 would limit the amount of money Defendants would make selling the products. Defendants’ object
19 was accomplished not only through a misleading label, but through a comprehensive scheme of
20 selective misleading research and testing, failure to test, false advertising, and deceptive omissions as
21 more fully alleged throughout this pleading. Parents were denied the right to make an informed
22 decision about whether to purchase and Defendants’ Baby Food for their children, knowing the full
23 risks attendant to that use. Such conduct was done with conscious disregard of Plaintiff’s rights.

24 46. Accordingly, Plaintiff requests punitive damages against the Defendants for the harms
25 caused to Plaintiff.

26 **PLAINTIFF-SPECIFIC ALLEGATIONS**

27 47. Plaintiff was diagnosed with ASD at approximately four years of age.

28 48. Plaintiff started consuming Baby Food products manufactured and/or sold by the

1 Defendants in approximately 2015 and consumed Defendants' Baby Food products at various times
2 through early childhood.

3 49. Upon information and belief, the Baby Food products manufactured/marketed by
4 Defendants and consumed by Plaintiff were all contaminated with substantial quantities of Toxic
5 Heavy Metals, namely lead, arsenic, and mercury – exceeding that of any regulatory limits.

6 50. Upon information and belief, as a direct and proximate result of consuming Defendants'
7 Baby Foods, Plaintiff was exposed to substantial quantities of Toxic Heavy Metals, namely lead,
8 arsenic, and mercury.

9 51. As a direct and proximate result of consuming Defendants' Baby Foods and the
10 exposure to the Toxic Heavy Metals therein – Plaintiff suffered brain injury which manifested as ASD
11 and related *sequelae*.

12 52. Based on prevailing scientific evidence, exposure to the Toxic Heavy Metals at the
13 levels contained in Defendants' Baby Foods can cause brain injury which can manifest as the
14 neurodevelopmental disorders ASD and related *sequelae* in humans.

15 53. Had any Defendant warned Plaintiff's carers that Defendants' Baby Foods could lead
16 to exposure to Toxic Heavy Metals or, in turn, brain injury, Plaintiff would not have consumed the
17 Baby Foods.

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

22 **CAUSES OF ACTION**

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

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

26 56. At all relevant times, Defendants engaged in the business of researching, testing,
27 developing, designing, manufacturing, labeling, marketing, selling, inspecting, distributing, and
28 promoting Baby Foods, which are defective and unreasonably dangerous to consumers, including

1 Plaintiff, because they do not contain adequate warnings or instructions concerning the dangerous
2 characteristics of Baby Foods and Toxic Heavy Metals. These actions were under the ultimate control
3 and supervision of Defendants. At all relevant times, Defendants registered, researched, manufactured,
4 distributed, marketed, and sold Baby Foods and aimed at a consumer market.

5 57. Defendants researched, tested, developed, designed, manufactured, labeled, marketed,
6 sold, inspected, distributed, and promoted, and otherwise released into the stream of commerce their
7 Baby Foods, and in the course of same, directly advertised or marketed the products to consumers and
8 end users, including Plaintiff, and therefore had a duty to warn of the risks associated with the
9 consumption of Baby Foods.

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

16 59. At the time of manufacture, Defendants could have provided the warnings or
17 instructions regarding the full and complete risks of Baby Foods because they knew or should have
18 known of the unreasonable risks of harm associated with the use of and/or exposure to such products.

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

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

1 during the time period Plaintiff consumed Baby Foods were vague, incomplete or otherwise
2 inadequate, both substantively and graphically, to alert consumers to the severe health risks associated
3 with Baby Foods consumption.

4 62. Defendants knew or should have known that their products created significant risks of
5 serious bodily harm to consumers, as alleged herein, and Defendants failed to adequately warn or
6 instruct consumers, i.e., the reasonably foreseeable users, of the risks of exposure to their products.
7 Defendants failed to warn and have wrongfully concealed information concerning the dangerous level
8 of Toxic Heavy Metals in their Baby Foods and the potential for consumed Baby Foods to expose
9 children to Toxic Heavy Metals, and further, have made false and/or misleading statements concerning
10 the safety of Baby Foods.

11 63. At all relevant times, Defendants' Baby Foods reached the intended consumers,
12 handlers, and users or other persons coming into contact with these products, including Plaintiff,
13 without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and
14 marketed by Defendants.

15 64. Plaintiff was exposed to Defendants' Baby Foods without knowledge of their dangerous
16 characteristics.

17 65. At all relevant times, Plaintiff was exposed to Defendants' Baby Foods while using
18 them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous
19 characteristics.

20 66. Plaintiff could not have reasonably discovered the defects and risks associated with
21 Baby Foods prior to or at the time of Plaintiff consuming Baby Foods. Plaintiff relied upon the skill,
22 superior knowledge, and judgment of Defendants to know about and disclose serious health risks
23 associated with using Defendants' products.

24 67. Defendants knew or should have known that the information disseminated with their
25 Baby Foods were inadequate, failed to communicate adequate information on the dangers of
26 consumption, and failed to communicate warnings and instructions that were appropriate and adequate
27 to render the products safe for their ordinary, intended and reasonably foreseeable uses.

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

1 warnings, hazards, and precautions that would have enabled consumers such as Plaintiff to avoid
2 consuming the products. Instead, Defendants disseminated information that was inaccurate, false, and
3 misleading, and which failed to communicate accurately or adequately the comparative severity,
4 duration, and extent of the risk of injuries with use of and/or exposure to Baby Foods; continued to
5 aggressively promote the safety of their products, even after they knew or should have known of the
6 unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed, through
7 aggressive marketing and promotion, any information or research about the risks and dangers of
8 consuming Baby Foods.

9 69. This alleged failure to warn is not limited to the information contained on Baby Foods
10 labeling. The Defendants were able, in accord with federal law, to comply with relevant state law by
11 disclosing the known risks associated with Baby Foods through other non-labeling mediums, *i.e.*,
12 promotion, advertisements, public service announcements, and/or public information sources. But the
13 Defendants did not disclose these known risks through any medium. The ability to provide such
14 warnings is not prohibited by any federal law.

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

17 71. Had Defendants provided adequate warnings and instructions and properly disclosed
18 and disseminated the risks associated with their Baby Foods, Plaintiff could have avoided the risk of
19 developing injuries and could have obtained or used alternative products. However, as a result of
20 Defendants' concealment of the dangers posed by their Baby Foods, Plaintiff could not have averted
21 his injuries.

22 72. Defendants' conduct, as described above, was reckless. Defendants risked the lives of
23 babies and children, including Plaintiff, with knowledge of the safety problems associated with Baby
24 Foods, and suppressed this knowledge from the general public. Defendants made conscious decisions
25 not to redesign, warn or inform the unsuspecting public. Defendants' reckless conduct warrants an
26 award of punitive damages.

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

1 74. As a direct and proximate result of the Defendants' failure to provide an adequate
2 warning of the risks of Baby Foods, Plaintiff has been injured, sustained severe and permanent pain,
3 suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but
4 not limited to past and future medical expenses, lost income, and other damages.

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

8 **COUNT II: STRICT PRODUCTS LIABILITY – DESIGN DEFECT**

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

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

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

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

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

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

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

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

8 When placed in the stream of commerce, Defendants' Baby Food products were unreasonably
9 dangerous in that they were hazardous and posed a grave risk of causing brain injury that manifests as
10 the neurodevelopmental disorders ASD and related *sequalae* when used in a reasonably anticipated
11 manner due to the substantial quantities of Toxic Heavy Metals in the Baby Foods; When placed in the
12 stream of commerce, Defendants' Baby Food products contained unreasonably dangerous design
13 defects and were not reasonably safe when used in a reasonably anticipated or intended manner;
14 Defendants did not sufficiently test, investigate, or study their Baby Food products; Exposure to the
15 Toxic Heavy Metals in Defendants' Baby Food products present a risk of harmful effects that outweigh
16 any potential utility stemming from their use; Defendants knew or should have known at the time of
17 marketing Baby Food products that exposure to their Baby Food products could result in brain injury
18 that manifests as ASD and related *sequalae* in children; Defendants did not conduct adequate post-
19 marketing surveillance of their Baby Food products; and Defendants could have employed safer
20 alternative designs and formulations.

21 84. Plaintiff consumed Defendants' Baby Food products in an intended or reasonably
22 foreseeable manner without knowledge of their dangerous characteristics.

23 85. Defendants' Baby Food products were and are more dangerous than alternative
24 products, and Defendants could have designed their Baby Food products to avoid harm to children.
25 Indeed, at the time Defendants designed the Baby Food products, the state of the industry's scientific
26 knowledge was such that a less risky design or formulation was attainable.

27 86. At the time the Baby Food products left Defendants' control, there was a practical,
28 technically feasible and safer alternative design that would have prevented the harm without

1 substantially impairing the reasonably anticipated or intended function of Defendants' Baby Foods, as
2 for example, demonstrated by Hain's presentation to the FDA wherein Hain acknowledges the risk
3 posed by specific ingredients in its Baby Foods.

4 87. Defendants have intentionally and recklessly defectively designed the Baby Foods with
5 wanton and willful disregard for the rights and health of the Plaintiff, and with malice, placing their
6 economic interests above the health and safety of the Plaintiff.

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

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

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

16 **COUNT III: STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT**

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

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

21 92. At all relevant times, the Baby Foods consumed by Plaintiff was expected to and did
22 reach Plaintiff without a substantial change in its condition as manufactured, handled, distributed, and
23 sold by Defendants.

24 93. At all relevant times, the Baby Foods consumed by Plaintiff was used in a manner that
25 was foreseeable and intended by Defendants.

26 94. The Baby Foods consumed by Plaintiff was not reasonably safe for their intended use
27 and were defective with respect to their manufacture, as described herein, in that Defendants deviated
28 materially from their design and manufacturing specifications and/or such design and manufacture

1 posed an unreasonable risk of harm to Plaintiff.

2 95. The Defendants' Baby Foods are inherently dangerous and defective, unfit and unsafe
3 for its intended and reasonably foreseeable uses, and do not meet or perform to the expectations of
4 parents or children.

5 96. The Baby Foods create risks to the health and safety of babies that are far more
6 significant and devastating than the risks posed by other baby food products, and which far outweigh
7 the utility of the Baby Foods products because of Defendants' manufacturing defects, which included
8 but were not limited to: Failure to adequately inspect/test the Baby Foods during the manufacturing
9 process; Failure to implement procedures that would reduce or eliminate the levels of Toxic Heavy
10 Metals in Baby Foods; Failure to avoid using ingredients free from, or which contain far less, Toxic
11 Heavy Metals to manufacture Baby Foods.

12 97. Defendants have intentionally and recklessly manufactured the Baby Foods with
13 wanton and willful disregard for the rights and health of the Plaintiff, and with malice, placing their
14 economic interests above the health and safety of the Plaintiff.

15 98. The manufacturing defects in Defendants' Baby Foods were substantial factors in
16 causing Plaintiff's injuries.

17 99. As a direct and proximate result of the Defendants' defective manufacture of the Baby
18 Foods, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability,
19 impairment, loss of enjoyment of life, economic loss and damages including, but not limited to medical
20 expenses, lost income, and other damages.

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

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

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

27 101. At all relevant times, Defendants engaged in the business of testing, developing,
28 designing, manufacturing, marketing, selling, distributing, and promoting Baby Foods. Defendants

1 knew or by the exercise of reasonable care should have known that their Baby Foods are not
2 accompanied with adequate warnings concerning the dangerous characteristics of Baby Foods and
3 Toxic Heavy Metals. These actions were under the ultimate control and supervision of Defendants.

4 102. Defendants researched, developed, designed, tested, manufactured, inspected, labeled,
5 distributed, marketed, promoted, sold, and otherwise released into the stream of commerce their Baby
6 Foods, and in the course of same, directly advertised or marketed the products to consumers and end
7 users, including Plaintiff, and therefore had a duty to warn of the risks associated with the use of Baby
8 Foods.

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

15 104. At the time of manufacture, Defendants could have provided warnings regarding the
16 full and complete risks of Baby Foods and Toxic Heavy Metals because they knew or should have
17 known use of Baby Foods was dangerous, harmful and injurious when used by Plaintiff in a reasonably
18 foreseeable manner.

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

22 106. Defendants knew or should have known that Baby Foods posed a grave risk of harm,
23 but failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure
24 to the products. The dangerous propensities of their products and the characteristics of Toxic Heavy
25 Metals contained in substantial amounts in their Baby Foods, as described above, were known to
26 Defendants, or scientifically knowable to Defendants through appropriate research and testing by
27 known methods, at the time they distributed, supplied or sold the product, and were not known to end
28 users and consumers, such as the Plaintiff.

1 107. Defendants further breached their duty by failing to use reasonable care to adequately
2 warn or instruct consumers (*i.e.*, the reasonably foreseeable users) of the risks of exposure to their
3 products. Defendants failed to warn and have wrongfully concealed information concerning the
4 dangerous level of Toxic Heavy Metals in their Baby Foods and the potential for consumed Baby Foods
5 to expose babies and toddlers to Toxic Heavy Metals, and further, have made false and/or misleading
6 statements concerning the safety of Baby Foods.

7 108. At all relevant times, Plaintiff was exposed to excessive levels of Toxic Heavy Metals
8 through consumption of Toxic Heavy Metals while using them for their intended or reasonably
9 foreseeable purposes, without knowledge of their dangerous characteristics.

10 109. Defendants knew or should have known that the minimal warnings disseminated with
11 their Baby Foods were inadequate, failed to communicate adequate information on the dangers and
12 safe use/exposure, and failed to communicate warnings and instructions that were appropriate and
13 adequate to render the products safe for their ordinary, intended and reasonably foreseeable uses.

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

23 111. A reasonable company under the same or similar circumstance would have warned and
24 instructed of the dangers of Baby Foods and Toxic Heavy Metals contained therein.

25 112. This alleged failure to warn is not limited to the information contained on the labeling
26 of Defendants' Baby Foods. Defendants were able, in accord with federal law, to comply with relevant
27 state law by disclosing the known risks associated with Baby Foods and Toxic Heavy Metals through
28 other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or

1 public information sources. But the Defendants did not disclose these known risks through any
2 medium.

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

5 114. Had Defendants provided adequate warnings and instructions and properly disclosed
6 and disseminated the risks associated with their Baby Foods, Plaintiff could have avoided the risk of
7 developing injuries and could have obtained or used alternative products. However, as a result of
8 Defendants' concealment of the dangers posed by their Baby Foods, Plaintiff could not have averted
9 his injuries.

10 115. Defendants' conduct, as described above, was reckless. Defendants risked the lives of
11 consumers and users of their products, including Plaintiff, with knowledge of the safety problems
12 associated with Baby Foods, and suppressed this knowledge from the general public. Defendants made
13 conscious decisions not to redesign, warn or inform the unsuspecting public. Defendants' reckless
14 conduct warrants an award of punitive damages.

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

17 117. As a direct and proximate result of the Defendants' failure to provide an adequate
18 warning of the risks of Baby Foods, Plaintiff has been injured, sustained severe and permanent pain,
19 suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but
20 not limited to past and future medical expenses, lost income, and other damages.

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

24 **COUNT V: NEGLIGENT PRODUCT DESIGN**

25 119. The Defendants knew or, by the exercise of reasonable care, should have known,
26 ordinary consumers such as Plaintiff would not have realized the potential risks and dangers of Baby
27 Foods.

28 120. The Defendants owed a duty to all reasonably foreseeable users to design a safe product.

1 121. The Defendants breached their duty by failing to use reasonable care in the design of
2 Baby Foods because the product exposed users to unsafe levels of Toxic Heavy Metals.

3 122. The Defendants breached their duty by failing to use reasonable care in the design of
4 Baby Foods by negligently designing the Baby Foods with ingredients and/or components high in
5 Toxic Heavy Metals.

6 123. The Defendants breached their duty by failing to use reasonable care in the design of
7 Baby Foods by negligently designing and formulation, in one or more of the following ways:

8 When placed in the stream of commerce, Defendants' Baby Foods were defective in design and
9 formulation, and, consequently, dangerous to an extent beyond that which an ordinary consumer would
10 contemplate;

11 When placed in the stream of commerce, Defendants' Baby Foods were unreasonably
12 dangerous in that they were hazardous and posed a grave risk of neurodevelopmental disorders and
13 other serious illnesses when used in a reasonably anticipated manner;

14 When placed in the stream of commerce, Defendants' Baby Foods contained unreasonably
15 dangerous design defects and were not reasonably safe when used in a reasonably anticipated or
16 intended manner;

17 Defendants did not sufficiently test, investigate, or study their Baby Foods and, specifically, the
18 content of Toxic Heavy Metals in the ingredients used to manufacture the foods and/or the finished
19 products;

20 Defendants did not sufficiently test, investigate, or study their Baby Foods and, specifically, the
21 ability for Baby Foods to expose babies to high amounts of Toxic Heavy Metals;

22 Exposure to Baby Foods presents a risk of harmful effects that outweigh any potential utility
23 stemming from the use of the products;

24 Defendants knew or should have known at the time of marketing Baby Foods that exposure to
25 Toxic Heavy Metals contained in the Baby Foods could result in brain injury that manifests as ASD
26 and other severe illnesses and injuries;

- 27 a. Defendants did not conduct adequate post-marketing surveillance of their Baby
28 Foods; and

1 b. Defendants could have employed safer alternative designs and formulations. For
 2 example, the Defendants could have avoided use of certain ingredients high in
 3 Toxic Heavy Metals, avoided using pre-mix vitamins high in Toxic Heavy
 4 Metals, and/or sampled their ingredients from other sources.

5 124. The Defendants breached their duty by failing to use reasonable care by failing to use
 6 cost effective, reasonably feasible alternative designs. There was a practical, technically feasible, and
 7 safer alternative design that would have prevented the harm without substantially impairing the
 8 reasonably anticipated or intended function of Defendants’ Baby Foods.

9 125. A reasonable company under the same or similar circumstances would have designed a
 10 safer product.

11 126. Plaintiff was harmed directly and proximately by the Defendants’ failure to use
 12 reasonable care in the design of their Baby Foods. Such harm includes significant exposure to a Toxic
 13 Heavy Metals, which can cause or contribute to brain injury that manifests as ASD and related
 14 *sequalae*.

15 127. Defendants’ defective design of Baby Foods was willful, wanton, malicious, and
 16 conducted with reckless disregard for the health and safety of consumers of the Baby Foods, including
 17 Plaintiff.

18 128. The defects in Defendants’ Baby Foods were substantial factors in causing Plaintiff’s
 19 injuries.

20 129. As a direct and proximate result of the Defendants’ defective design of the Baby Foods,
 21 Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss
 22 of enjoyment of life, economic loss and damages including, but not limited to past and future medical
 23 expenses, lost income, and other damages.

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

27 **COUNT VI: NEGLIGENT MANUFACTURING**

28 131. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as

1 if fully stated herein.

2 132. At all relevant times, the Defendants manufactured, tested, marketed, sold, and
3 distributed the Baby Foods that Plaintiff consumed.

4 133. The Defendants had a duty to exercise reasonable care, in the manufacturing, testing,
5 marketing, sale, and distribution of Baby Foods.

6 134. The Defendants knew or, by the exercise of reasonable care, should have known, use of
7 Baby Foods were carelessly manufactured, dangerous, harmful and injurious when used by Plaintiff in
8 a reasonably foreseeable manner.

9 135. The Defendants knew or, by the exercise of reasonable care, should have known,
10 ordinary consumers such as Plaintiff would not have realized the potential risks and dangers of Baby
11 Foods improperly manufactured, tested, marketed, distributed, and sold.

12 136. Without limitation, examples of the manner in which Defendants breached their duty to
13 exercise reasonable care in manufacturing Baby Foods, included:

- 14 a. Failure to adequately inspect/test the Baby Foods during the manufacturing
15 process;
- 16 b. Failure to implement procedures that would reduce or eliminate levels of Toxic
17 Heavy Metals in Baby Foods; and
- 18 c. Failure to avoid using ingredients free from, or which contain far less, Toxic
19 Heavy Metals to manufacture Baby Foods.

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

23 138. Plaintiff was harmed directly and proximately by the Defendants' failure to use
24 reasonable care in the manufacture of their Baby Foods. Such harm includes significant exposure to a
25 Toxic Heavy Metals, which can cause or contribute to brain injury which manifests as ASD and related
26 *sequelae*.

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

1 Plaintiff.

2 140. The defects in Defendants' Baby Foods were substantial factors in causing Plaintiff's
3 injuries.

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

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

11 **JURY TRIAL DEMAND**

12 143. Plaintiff demands a trial by jury on all the triable issues within this pleading.

13 **PRAYER FOR RELIEF**

14 144. **WHEREFORE**, Plaintiff requests the Court to enter judgment in Plaintiff's favor and
15 against the Defendants for:

- 16 a. actual or compensatory damages in such amount to be determined at trial and as
17 provided by applicable law;
- 18 b. exemplary and punitive damages sufficient to punish and deter the Defendants and
19 others from future wrongful practices;
- 20 c. pre-judgment and post-judgment interest;
- 21 d. costs including reasonable attorneys' fees, court costs, and other litigation expenses;
22 and
- 23 e. any other relief the Court may deem just and proper.
- 24

25 Dated: March 20, 2024

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