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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

AG; HG; and XG, individually and represented by their mother and *guardian ad litem* VALENCIA GIBSON,

Plaintiffs,

v.

PLUM, PBC; HAIN CELESTIAL GROUP, INC.; GERBER PRODUCTS COMPANY; NURTURE, INC; BEECH-NUT NUTRITION COMPANY; AND SPROUT FOODS INC.,

Defendants.

Case No.

COMPLAINT

DEMAND FOR JURY TRIAL

TABLE OF CONTENTS

INTRODUCTION

1. This case involves a group of manufacturers—namely Plum, PBC; Hain Celestial Group, Inc.; Gerber Products Company; Nurture, Inc; Beech-Nut Nutrition Company; and Sprout Foods Inc. ("Defendants" or "Defendant Baby Food Manufacturers")—that *knowingly* sold baby food products ("Baby Foods") which contain dangerous levels of toxic heavy metals—mercury, lead, arsenic, and cadmium (collectively "Toxic Heavy Metals"), which are all known to be severe neurotoxins—and how such toxic exposures substantially contributed to Plaintiffs developing lifelong brain damage and neurodevelopmental disorders. Plaintiffs AG, HG, and XG ("Plaintiffs") are three small siblings who live with debilitating Autism Spectrum Disorder ("ASD") because they consumed poisonous Baby Foods manufactured and sold by these Defendants. This case seeks to hold the Defendant Baby Food Manufacturers accountable for their reprehensible conduct and ensure they are punished for permanently affecting Plaintiffs' ability to live a fulfilling life.

2. That Defendants' Baby Foods are laced with staggering amounts of Toxic Heavy Metals recently made headlines following research and a Congressional investigation. In February 2021, the U.S. House of Representatives' Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform released a report containing shocking details of Defendants' tainted Baby Foods based on the submission of internal test results and company documents. Specifically, the Subcommittee found that Defendants sell Baby Foods containing as much as 180 parts per billion ("ppb")[1] inorganic arsenic, 6441 ppb lead, 10 ppb mercury, and manufacture their Baby Foods using ingredients containing as much as 913.4 ppb arsenic, 886.9 ppb lead, and 344.55 ppb cadmium, far eclipsing domestic and international regulatory standards. By way of comparison, the U.S. Food and Drug Administration ("FDA") has set the maximum allowable levels in bottled water at 10 ppb inorganic arsenic, 5 ppb lead, and 5 ppb cadmium, and the U.S. Environmental Protection Agency ("EPA") has capped the allowable level of mercury in drinking water at 2 ppb.

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

With a chilling note the Subcommittee concluded that "[m]anufacturers *knowingly* sell these products to unsuspecting parents, in spite of internal company standards and test results, and without any warning labeling whatsoever."[2] (emphasis added).

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

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

PARTIES

I. Plaintiffs

5. Plaintiffs are citizens of Arizona and no other state.

II. Defendants

6. Defendant Plum, PBC ("Plum") is a citizen of Delaware and California with its principal place of business located at 1485 Park Avenue, Suite 200, Emeryville, California. Plum sells Baby Foods under the brand name Plum Organics. Plum's products are divided into groups according to the targeted infant or toddler age and/or type of food product. For example, there are five groups designated for the youngest infants: Stage 1 (4+ months old), Stage 2 (6+ months old),

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[2] Staff Report, Subcommittee on Economic and Consumer Policy Committee on Oversight and 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: https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-02-04%20ECP%20Baby%20Food%20Staff%20Report.pdf.

Stage 3 (6+ months old), "Super Puffs", and "Little Teethers". At all relevant times, Plum has conducted business and derived substantial revenue from its manufacturing, advertising, distributing, selling, and marketing of Baby Foods within this judicial district.

7. Defendant Nurture, Inc ("Nurture"), is a citizen of Delaware and New York with its principal place of business located at 40 Fulton St, 17th Floor, New York, NY 10038-1850. Nurture owns Happy Family Brands (including Happy Family Organics) and sells Baby Foods under the brand name HappyBaby. Nurture classifies its HappyBaby range of products according to three categories: "baby", "tot", and "mama". The "baby" category is comprised of foods, including "starting solids", intended for age groups 0-7+ months, the "tot" category covers 12+ months, and "mama" includes infant formulas for newborn babies. At all relevant times, Nurture has conducted business and derived substantial revenue from its manufacturing, advertising, distributing, selling, and marketing of HappyBaby within this judicial district.

8. Defendant Beech-Nut Nutrition Company ("Beech-Nut") is a citizen of Delaware and New York with its principal place of business located at 1 Nutritious Pl., Amsterdam, NY 12010. Beech-Nut sells Baby Foods under the brand name Beech-Nut. Beech-Nut produces Baby Foods aimed at infants 4+ months up to 12+ months and includes a variety of cereals, "jars", and "pouches" for these age groups. At all relevant times, Beech-Nut has conducted business and derived substantial revenue from its manufacturing, advertising, distributing, selling, and marketing of Baby Foods within this judicial district.

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

10. Defendant Gerber Products Company ("Gerber") is a citizen of Michigan with its principal place of business located at 445 State Street, Fremont, MI 49413-0001. Gerber sells Baby

Foods under the brand name Gerber. Gerber organizes its products into broad categories of "formula", "baby cereal", "baby food", "snacks", "meals & sides" "beverages" and "organic". At all relevant times, Gerber has conducted business and derived substantial revenue from its manufacturing, advertising, distributing, selling, and marketing of Baby Foods within this judicial district.

11. Defendant Sprout Foods, Inc. ("Sprout") is a citizen of Delaware and New Jersey with its principal place of business located at 50 Chestnut Ridge Rd, Montvale, NJ 07645. Sprout sells Baby Foods under the brand name Sprout Organic Foods. Sprout organizes its Baby Foods selection according to three categories: Stage 2 (6 months+); Stage 3 (8 months+); and Toddler. At all relevant times, Sprout has conducted business and derived substantial revenue from its manufacturing, advertising, distributing, selling, and marketing of Baby Foods within this judicial district.

JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332. There is complete diversity of citizenship between the parties. In addition, Plaintiffs seek damages in excess of $75,000, exclusive of interest and costs.

13. This Court has personal jurisdiction over Plum because Plum is a citizen of the State of California and resides within this judicial district. The Court has personal jurisdiction over Hain, Nurture, Gerber, Beech-Nut, and Sprout insofar as each Defendant is authorized and licensed to conduct business in the State of California, maintains and carries on systematic and continuous contacts in this judicial district, regularly transacts business within this judicial district, and regularly avails itself of the benefits of this judicial district.

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

15. Venue is proper in this Court pursuant to 28 U.S.C. §1391 because all Defendants are subject to the Court's personal jurisdiction within this district. Plum is headquartered within this judicial district and all Defendants maintain continuous, regular, and systematic contacts within this

judicial district.

16. Additionally, the Court has pendent personal jurisdiction over all Defendants.

FACTUAL ALLEGATIONS

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

17. 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"[3], published a report investigating the presence of Toxic Heavy Metals in baby foods.[4] 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."[5] 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 baby food companies as particularly high in Toxic Heavy Metals.[6]

18. The results of the HBBF report were consistent with that of the FDA which had, in 2017, detected one or more of the four Toxic Heavy Metals in 33 of 39 types of baby food tested.[7] 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."[8] To that end, the HBBF, along with other concerned stakeholders, urged the FDA to, among other

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[3] https://www.hbbf.org/solutions.
[4] 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).
[5] *Id.* at 6.
[6] *Id.* at 10-11
[7] *Id.* at 6.
[8] *Id.* at 6.

measures, "[s]et health-protective standards for heavy metals, prioritizing foods that offer FDA the greatest opportunity to reduce exposure, considering additive effects of the multiple metals detected in foods, and explicitly protecting against neurodevelopmental impacts… Implement a proactive testing program for heavy metals in foods consumed by babies and toddlers…[and] [e]stablish a goal of no measurable amounts of cadmium, lead, mercury, and inorganic arsenic in baby and children's food, in recognition of the absence of a known safe level of exposure, and work with manufacturers to achieve steady progress."[9] The HBBF also invited baby food manufacturers to share its goal of reducing "heavy metals in baby food to levels as low as reasonably achievable."[10]

19. 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 and cadmium concentrations in a large convenience sample of US baby foods."[11] The study detected lead in 37% of samples, and cadmium in 57%.[12] This was consistent with findings by researchers examining baby food products in other parts of the world. In December 2019, Brazilian researchers observed that "[i]norganic contaminants, including those commonly known as 'heavy metals' (cadmium, arsenic, lead and mercury)…may be present in baby foods such as infant formulas, cereals, snacks, prepared meals, and jarred fruits and vegetables."[13] And, in 2011 Swedish scientists from the renowned Karolinska Institute noted that that "[h]igh levels of arsenic in [infant] rice-based foods are of concern."[14]

II. Congressional Investigation Finds Substantial Presence of Heavy Metals in Baby Foods

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[9] *Id*. at 8-9.
[10] *Id*. at 9
[11] Gardener, et al., *Lead and cadmium contamination in a large sample of United States infant 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.
[12] *Id*.
[13] De Paiva, *et al*., *Occurrence and determination of inorganic contaminants in baby food and infant formula*, 30 CURR. OPIN. FOOD SCI. (2019), available at: https://www.sciencedirect.com/science/article/abs/pii/S2214799318301565#!.
[14] Bjorklund, et al., *High concentrations of essential and toxic elements in infant formula and infant foods - A matter of concern* 127 FOOD. CHEM (2011), available at: https://www.researchgate.net/publication/228471005_High_concentrations_of_essential_and_toxic_elements_in_infant_formula_and_infant_foods_-_A_matter_of_concern/citation/download.

Sparking National Outrage

20. On February 4, 2021, the U.S. House of Representatives' Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, published a report detailing its findings that Toxic Heavy Metals—including arsenic, cadmium, lead, and mercury—were present in "significant levels" in numerous commercial baby food products.[15] Four companies—Hain, Gerber, Nurture, and Beech-Nut —produced internal testing policies, test results for ingredients and finished products, and documentation about what the companies did with ingredients and/or finished products that exceeded their internal testing limits. Three companies—Plum, [16] Walmart, and Sprout—refused to cooperate.[17]

21. The Subcommittee reported that the data submitted by the companies unequivocally revealed that a substantial number of Defendants' finished products and/or ingredients used to manufacture the Baby Foods are tainted with significant levels of Toxic Heavy Metals, namely inorganic arsenic, lead, cadmium, and mercury.[18]

22. Specifically, the Subcommittee concluded that:

ARSENIC was present in baby foods made by all responding companies:

a. Nurture (HappyBABY) sold baby foods after tests showed they contained as much as 180 parts per billion (ppb) inorganic arsenic. Over 25% of the products Nurture tested before sale contained over 100 ppb inorganic arsenic. Nurture's testing shows that the typical baby food product it sold contained 60 ppb inorganic arsenic.

b. Beech-Nut used ingredients after they tested as high as 913.4 ppb arsenic. Beech-Nut routinely used high-arsenic additives that tested over 300 ppb

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[15] *See generally* Subcommittee Rpt.
[16] Plum's parent corporation, Campbell's, responded to the Subcommittee's inquiries, and the Subcommittee Report references the parent corporation as opposed to Plum. However, as Plum is the Defendant in this lawsuit, any references to the Subcommittee's findings regarding Campbell are attributed to Plum. The same Baby Foods are at issue.
[17] Subcommittee Rpt. at 2.
[18] *Id*. at 2-3.

arsenic to address product characteristics such as "crumb softness."

c. Hain (Earth's Best Organic) sold finished baby food products containing as much as 129 ppb inorganic arsenic. Hain typically only tested its ingredients, not finished products. Documents show that Hain used ingredients testing as high as 309 ppb arsenic.

d. Gerber used high-arsenic ingredients, using 67 batches of rice flour that had tested over 90 ppb inorganic arsenic.

LEAD was present in baby foods made by all responding companies:

a. Nurture (HappyBABY) sold finished baby food products that tested as high as 641 ppb lead. Almost 20% of the finished baby food products that Nurture tested contained over 10 ppb lead.

b. Hain (Earth's Best Organic) used ingredients containing as much as 352 ppb lead. Hain used many ingredients with high lead content, including 88 that tested over 20 ppb lead and six that tested over 200 ppb lead.

c. Beech-Nut used ingredients containing as much as 886.9 ppb lead. It used many ingredients with high lead content, including 483 that contained over 5 ppb lead, 89 that contained over 15 ppb lead, and 57 that contained over 20 ppb lead.

d. Gerber used ingredients that tested as high as 48 ppb lead; and used many ingredients containing over 20 ppb lead.

CADMIUM was present in baby foods made by all responding companies:

a. Beech-Nut used 105 ingredients that tested over 20 ppb cadmium. Some tested much higher, up to 344.55 ppb cadmium.

b. Hain (Earth's Best Organic) used 102 ingredients in its baby food that tested over 20 ppb cadmium. Some tested much higher, up to 260 ppb cadmium.

c. Sixty-five percent of Nurture (HappyBABY) finished baby food products contained more than 5 ppb cadmium.

d. Seventy-five percent of Gerber's carrots contained cadmium in excess of 5

ppb, with some containing up to 87 ppb cadmium.

MERCURY:

a. Nurture (HappyBABY) sold finished baby food products containing as much as 10 ppb mercury.

b. Gerber rarely tests for mercury in its baby foods and Hain (Earth's Best Organic) and Beech-Nut do not even test for mercury in baby food.[19] However, independent testing by HBBF of Hain's Baby Foods confirm that Hain's products contain as much as 2.4 ppb of mercury.[20]

23. These levels greatly surpass the limits allowed by U.S. regulatory agencies. Upon information and belief, there are no FDA regulations governing the presence of Toxic Heavy Metals in Baby Foods specifically; to the extent such regulations exist, the quantities of Toxic Heavy Metals in Defendants' Baby Foods far exceed any permissible FDA levels. To be sure, the FDA has set the maximum contaminant levels ("MCL") in bottled water at 10 ppb inorganic arsenic, 5 ppb lead, and 5 ppb cadmium, and the EPA has capped the allowable level of mercury in drinking water at 2 ppb. However, these limits were created in reference to *adult* exposure, not infants. Compared to these thresholds, the test results of the Defendants' Baby Foods and their ingredients are 91 times (903 ppb) greater than permitted arsenic levels, 177 times (881 ppb) greater than permitted lead levels, 70 times (339 ppb) greater than permitted cadmium levels, and 5 times (8 ppb) greater than permitted mercury levels.[21]

24. Moreover, compounding these troubling findings, the Defendants set internal limits for the presence of Toxic Heavy Metals in their foods that were, themselves, dangerously high and then routinely failed to abide by those inadequate standards. For example, the Subcommittee found that Hain (Earth's Best Organic) set an internal standard of 200 ppb for arsenic, lead, and cadmium in some of its ingredients. But Hain routinely exceeded its internal policies, using ingredients containing 353 ppb lead and 309 ppb arsenic. Hain justified these deviations based on "theoretical

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[19] *Id*. at 2-4.
[20] *See* HBBF Rpt. at 19.
[21] Subcommittee Rpt. at 3-4.

calculations," even after Hain admitted to the FDA that its testing *underestimated* final product toxic heavy metal levels.[22] Similarly, Beech-Nut set internal arsenic and cadmium standards at 3,000 ppb in additives, such as vitamin mix, and 5,000 ppb lead for certain ingredients like BAN 800. The Subcommittee observed that these standards are the highest of any responding manufacturer.[23]

25. As found by the Subcommittee, Defendants have willfully sold—and continue to sell—contaminated Baby Foods notwithstanding their full awareness of these unacceptably high levels of Toxic Heavy Metals in their products. In August 2019, Hain held a closed-door meeting with the FDA during which Hain delivered a presentation to the agency acknowledging the Toxic Heavy Metal problem in its Baby Food.[24] In the PowerPoint slides presented during the meeting—only made public by the Subcommittee—Hain confirmed that some of the ingredients in its Baby Food contain as much as between 108 to 129 ppb of arsenic, specifically noting "[p]reliminary investigation indicates Vitamin/Mineral Pre-Mix may be a major contributing factor"[25]. Additionally, the presentation revealed that:

a. Hain's corporate policy to test only ingredients, not final products, underrepresents the levels of toxic heavy metals in baby foods. In 100% of the Hain baby foods tested, inorganic arsenic levels were higher in the finished baby food than the company estimated they would be based on individual ingredient testing. Inorganic arsenic was between 28% and 93% higher in the finished products;

b. Many of Hain's baby foods were tainted with high levels of inorganic arsenic—half of its brown rice baby foods contained over 100 ppb inorganic arsenic; its average brown rice baby food contained 97.62 ppb inorganic arsenic; and

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[22] *Id*. at 4-5.
[23] Subcommittee Rpt. at 4.
[24] Hain, *PowerPoint Presentation to Food and Drug Administration: FDA Testing Result Investigation* (Aug. 1, 2019) ("2019 Hain & FDA Meeting"), available at: https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2.pdf).
[25] *Id*. at *9.

c. Naturally occurring toxic heavy metals may not be the only problem causing the unsafe levels of toxic heavy metals in baby foods; rather, baby food producers like Hain may be adding ingredients that have high levels of toxic heavy metals into their products, such as vitamin/mineral pre-mix.[26]

26. Moreover, although Plum and Sprout refused to cooperate with the Subcommittee's investigation, independent data confirms that the Baby Food of these companies is similarly tainted.

27. Instead of producing any substantive information, Plum provided the Subcommittee with a self-serving spreadsheet declaring that every one of its products "meets criteria",[27] while declining to state what the criteria were. Plum's disingenuous testing summary speaks volumes since the summary does not show the levels of Toxic Heavy Metals that the testing found or the levels that would "meet criteria." Disturbingly, Plum admitted that, for mercury (a powerful neurotoxin), the company has *no criterion* whatsoever, stating: "No specific threshold established because no high-risk ingredients are used."[28] However, despite Plum having no mercury threshold, it still marked every food as "meets criteria" for mercury. The Subcommittee noted that "[t]his misleading framing—of meeting criteria that do not exist—raises questions about what [Plum's] other thresholds actually are, and whether they exist."[29] Indeed, HBBF's independent testing confirms the presence of

[26] Subcommittee Report at 5-6
[27] Campbell, *Product Heavy Metal Test Results* (Dec. 11, 2019), available at: https://oversight.house.gov/sites/democrats.oversight.house.gov/files/12.pdf).
[28] *Id*. at 00046.
[29] Subcommittee Report at 45.

Toxic Heavy Metals in Plum's Baby Food:

Food	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)
Plum Organics Pumpkin Banana Papaya Cardamom, 6 months & up	2.4*	--	1.4*	2.4	<0.139
Plum Organics Apple, Raisin, & Quinoa Organic Baby Food- 2	5.6*	--	2.2	1.9	0.145*
Plum Organics Little Teethers Organic Multigrain Teething Wafers- Banana with Pumpkin- Baby Crawler	49.9	--	1.4*	6.3	0.726
Plum Organics Mighty Morning Bar- Blueberry Lemon- Tots, 15 months & up	40[9]	39	3.4	24.3	<0.137

28. Discovery will flesh out in greater detail the extent of Toxic Heavy Metals in Plum's Baby Foods.

29. Sprout did not respond to the Subcommittee at all. Again, the testing conducted by HBBF confirms that Sprout's Baby Foods are similarly tainted by substantial amounts of Toxic Heavy Metals:

Brand	Food	Food type	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)	Metro area where purchased	Retailer
Sprout	Organic Quinoa Puffs Baby Cereal Snack - Apple Kale	Snack - puffs, contains rice	107	47	39.3	41.5	1.31	Washington, DC	amazon.com
Sprout	Carrot Apple Mango Organic Baby Food - 2, 6 months & up	Fruit and veggie - mixed	6.1	--	2.1	15.1	< 0.131	Charlottesville, VA	Wegmans

30. As the Subcommittee noted, "[w]hether due to evasion or negligence, Sprout's failure to respond raises serious concerns about the presence of toxic heavy metals in its baby foods, as even limited independent testing has revealed the presence of toxic heavy metals in its products."[30]

[30] Subcommittee Rpt. at 46

Discovery will flesh out in greater detail the extent of Toxic Heavy Metals in Sprout's Baby Foods.

III. Pediatric ASD

31. Autism spectrum disorder ("ASD") is a developmental disability that can cause significant social, communication and behavioral challenges, particularly for children diagnosed with the disorder. ASD includes conditions that were previously considered separate—autism, Asperger's syndrome, childhood disintegrative disorder, and an unspecified form of pervasive developmental disorder. The CDC estimates that, as of 2016, 1 in 54 U.S. children have ASD.[31]

32. There is often nothing about how individuals with ASD look that sets them apart from other people, but those with ASD may communicate, interact, behave, and learn in ways that are different from most other people. The learning, thinking, and problem-solving abilities of people with ASD can range from gifted to severely challenged. Many people with ASD require substantial support in their daily lives, many children with ASD have difficulty learning, and some have signs of lower-than-normal intelligence.

33. A child with ASD may have problems with social interaction and communication skills:

a. Fails to respond to his or her name or appears not to hear others;

b. Resists cuddling and holding, and seems to prefer playing alone, retreating into his or her own world;

c. Has poor eye contact and lacks facial expression;

d. Does not speak or has delayed speech, or loses previous ability to say words or sentences;

e. Cannot start a conversation or keep one going, or only starts one to make requests or label items;

f. Speaks with an abnormal tone or rhythm and may use a singsong voice or robot-like speech;

[31]Centers for Disease Control and Prevention ("CDC"), *Data & Statistics on Autism Spectrum Disorder* (September 25, 2020), available at: https://www.cdc.gov/ncbddd/autism/data.html.

g. Repeats words or phrases verbatim, but does not understand how to use them;

h. Does not appear to understand simple questions or directions;

i. Does not express emotions or feelings and appears unaware of others' feelings;

j. Does not point at or bring objects to share interest;

k. Inappropriately approaches a social interaction by being passive, aggressive or disruptive;

l. Has difficulty recognizing nonverbal cues, such as interpreting other people's facial expressions, body postures or tone of voice;

34. Many children with ASD continue to have difficulty with language and social skills throughout the course of their lives, and the teen years can bring worse behavioral and emotional problems which may impose sever limitations to their quality of life.

35. Some children show signs of ASD in early infancy, such as reduced eye contact, lack of response to their name or indifference to caregivers. Other children may develop normally for the first few months or years of life, but then suddenly become withdrawn or aggressive or lose language skills they have acquired.

36. Environmental factors—such as exposure to Toxic Heavy Metals—have been found to play a key role in the development of ASD, with the CDC, Mayo Clinic and NIH all recognizing early life exposure to environmental toxins (such as lead) as risk factors for ASD.[32]

IV. Dangers of Toxic Heavy Metals to Babies and Children

37. According to the World Health Organization ("WHO"), Toxic Heavy Metals, specifically arsenic, cadmium, lead, and mercury, pose a "major public health concern" for children.[33] The Occupational Safety and Health Administration ("OSHA") has warned that these

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[32] Mayo Clinic, *Autism spectrum disorder*, available at: https://www.mayoclinic.org/diseases-conditions/autism-spectrum-disorder/symptoms-causes/syc-20352928; CDC, *What is Autism Spectrum Disorder?*, available at: https://www.cdc.gov/ncbddd/autism/facts.html; NIH, Autism *Spectrum Disorder Fact Sheet*, available at: https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Autism-Spectrum-Disorder-Fact-Sheet

[33] 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.

metals "may build up in biological systems and become a significant health hazard."[34] Indeed, the Department of Health and Human Services' Agency for Toxic Substances and Disease Registry ("ATSDR") ranks arsenic as number *one* among substances present in the environment that pose the most significant potential threat to human health, followed by lead (second), mercury (third), and cadmium (seventh).[35]

38. The threat presented by Toxic Heavy Metals to children's health is widely shared by the global scientific community. As one recent study observed, "[t]he implications of heavy metals with regards to children's health have been noted to be more severe compared to adults. The elements' 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."[36] 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%.[37] And, the mechanisms needed to metabolize and eliminate heavy metals are comparatively undeveloped in childhood, with babies having weaker detoxifying mechanisms and poorer immune systems than adults.[38] For example, liver pathways that in adulthood metabolize absorbed arsenic do not mature until mid-childhood; un-excreted arsenic thus continues to circulate and is deposited in other organs.[39] According to Linda McCauley, Dean of the Nell Hodgson Woodruff School of Nursing at Emory University, who studies environmental health

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[34] OSHA, *Toxic Metals*, available at: https://www.osha.gov/toxic-metals.
[35] ATSDR, *ATSDR's Substance Priority List* (2019), available at: www.atsdr.cdc.gov/spl/index.html#2019spl.
[36] Osman, et al., *Exposure routes and health effects of heavy metals on children*, 32 BIOMETALS 563–573 (2019), available at: https://link.springer.com/article/10.1007%2Fs10534-019-00193-5#citeas.
[37] Stein, et al., *In harm's way: toxic threats to child development*, 23 J DEV BEHAV PEDIATR.1 S13–S22 (2002).
[38] Gorini, et al., *The Role of Heavy Metal Pollution in Neurobehavioral Disorders: a Focus on Autism* 1 REV. J. AUTISM DEV. DISORD. 1, 354–372 (2014), available at: https://link.springer.com/article/10.1007/s40489-014-0028-3.
[39] 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://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-017-4808-4.

effects, "[n]o level of exposure to these [heavy] metals has been shown to be safe in vulnerable infants."[40] Thus, "the major windows of developmental vulnerability occur during infancy and early childhood due to continuing brain development after birth."[41] In short, even small amounts of exposure to Toxic Heavy Metals can have devastating health outcomes for babies and children.

A. Exposure to Toxic Heavy Metals Has Been Consistently Associated with Autism in Pediatric Populations

39. Multiple studies, reviews, and meta-analyses conducted throughout various parts of the world over the last decade have consistently observed a positive association between exposure to Toxic Heavy Metals and the development of ASD in children and infant populations.

40. In 2019, researchers at the University of Buffalo conducted a systematic review and meta-analysis of relevant published research on the association between children's exposure to inorganic arsenic and ASD.[42] The meta-analysis concluded that there is consistent evidence supporting a positive association between early life inorganic arsenic exposure and diagnosis of ASD, with the authors noting that "it is in the best interest of policy makers and the public to reduce exposures to [arsenic] among pregnant women and children."[43]

41. Similar results were observed in another systematic review and meta-analysis published in 2020 by researchers at the State University of New York.[44] This follow-up meta-analysis investigated the association of exposure to cadmium, mercury, and aluminum and ASD. The authors stated that they selected these metals "because they are abundant in our environment, are known to cause neurological problems in humans, and have multiple published studies examining

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[40] 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
[41] Gorini, et al. *supra*.
[42] Wang, et al., *Exposure to Inorganic Arsenic and Lead and Autism Spectrum Disorder in Children: A Systematic Review and Meta-Analysis*, 21 CHEM RES. TOXICOL. 32, 1904-1919 (2019), available at: https://pubmed.ncbi.nlm.nih.gov/31549506/.
[43] *Id*.
[44] Sulaiman, et al., *Exposure to Aluminum, Cadmium, and Mercury and Autism Spectrum Disorder in Children: A Systematic Review and Meta-Analysis*, 33 CHEM. RES. TOXICOL. 11, 2699-2718 (2020), available at: https://pubmed.ncbi.nlm.nih.gov/32990432/.

their potential links with ASD."[45] Specifically, the meta-analysis reviewed 18 studies on cadmium and 23 studies on mercury. When the studies were integrated into the analysis, the authors found significant associations between all the metals and ASD.[46] Notably, levels of mercury in hair, urine and blood were all positively associated with ASD. Overall, the authors concluded, "these findings support policies that advocate limiting exposure to neurotoxic metals, particularly for pregnant women and young children, in order to help reduce the rising incidence of ASD."[47]

42. An earlier meta-analysis from 2014 similarly concluded that environmental exposures to mercury in early infancy were significantly associated—almost a doubling of the risk—with the development of ASD.[48] Notably, the authors found that the summary odds ratios (risk of disease) were similar after excluding studies not adjusted for confounders. *Id.*

43. Similarly, a 2018 Chinese study observed that children with ASD had significantly higher levels of mercury and arsenic in their blood compared with healthy controls.[49] The authors proceeded to note "[t]he results of this study are consistent with numerous previous studies, supporting an important role for heavy exposure, particularly mercury, in the etiology of ASD."[50]

44. A 2017 longitudinal cohort study of Korean children measured the levels of mercury in the blood of children at ages 2 and 3.[51] The study authors observed elevated mercury levels in the blood of young children who were later diagnosed with ASD. Indeed, this study was specifically cited by the Subcommittee for the proposition that Toxic Heavy Metals increase the risk of autistic

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[45] *Id.*
[46] *Id.*
[47] *Id.*
[48] Yoshimasu, et al., *A meta-analysis of the evidence on the impact of prenatal and early infancy 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/.
[49] Li, et al., *Blood Mercury, Arsenic, Cadmium, and Lead in Children with Autism Spectrum Disorder*, 181 BIOL TRACE ELEM RES 31-37 (2018), available at: https://pubmed.ncbi.nlm.nih.gov/28480499/.
[50] *Id.*
[51] Ryu, et al., *Associations of prenatal and early childhood mercury exposure with autistic behaviors at 5 years of age: The Mothers and Children's Environmental Health (MOCEH) study*, 15 SCI. TOTAL ENVIRON. 251-257 (2017), available at: https://www.sciencedirect.com/science/article/abs/pii/S0048969717316479.

behaviors in pre-school children.[52]

45. In 2016 a multidisciplinary team comprised of researchers from the University of Texas, University of Utah, Johns Hopkins, University of South Florida, University of Alabama, and Rutgers University analyzed data on 4,486 children with ASD residing in 2,489 census tracts in five sites of the Centers for Disease Control and Prevention's Autism and Developmental Disabilities Monitoring ("ADDM") Network to assess whether ambient lead, mercury, and arsenic concentrations were associated with ASD prevalence.[53] Notably, as well as observing an association between ambient lead concentrations and ASD prevalence, the results demonstrated that exposure to multiple metals may have synergistic effects on ASD prevalence.[54] This is significant because children consuming Defendants' Baby Foods are exposed to repeated, high doses of multiple Toxic Heavy Metals, thereby compounding the risk of ASD. Indeed, recent research indicates that mercury has a threshold effect (the minimum dose of exposure prior to onset of disease) of greater than 15 ppb for the risk of ASD to manifest in an child, with one paper concluding that "[t]he weight of scientific evidence supports [mercury] as a causal factor in subjects diagnosed with an ASD."[55] Indeed, the available literature consistently observes a dose-response relationship between exposure to Toxic Heavy Metals and ASD, with increased dose resulting in more severe forms of ASD.[56]

46. Moreover, a 2015 study of lead and mercury levels in the bodies of Egyptian children concluded that the mean levels of mercury and lead in the hair of children diagnosed with autism were significantly higher than controls.[57] The authors specifically noted that "[e]nvironmental

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[52] Subcommittee Report at 13.
[53] Dickerson, et al., *Autism spectrum disorder prevalence and associations with air concentrations of lead, mercury, and arsenic*, 188 ENVIRON MONIT. ASSESS. 407 (2016).
[54] *Id*.
[55] Geier, et al., *Blood mercury levels in autism spectrum disorder: Is there a threshold level?* 70 ACTA NEUROBIOL. EXP. 177–186 (2010), available at: https://pubmed.ncbi.nlm.nih.gov/20628441/.
[56] *See* Rossignol, et al., *Environmental toxicants and autism spectrum disorders: a systematic review*, 4 TRANSL. PSYCHIATRY 2, 1-23 (2014), available at: https://pubmed.ncbi.nlm.nih.gov/24518398/.
[57] Mohamed, et al., *Assessment of Hair Aluminum, Lead, and Mercury in a Sample of Autistic Egyptian Children: Environmental Risk Factors of Heavy Metals in Autism* BEHAV. NEUROL. (2015), available at: https://pubmed.ncbi.nlm.nih.gov/26508811/.

exposure to these toxic heavy metals, at key times in development, may play a causal role in autism."[58]

47. A 2013 U.S. study investigated both the level of Toxic Heavy Metals in children with ASD and the possible association of the metals with ASD severity.[59] 55 children with autism at ages 5-16 were compared to 44 controls with similar age and gender.[60] After measuring Toxic Heavy Metals in whole blood, red blood cells and urine, the authors observed that the autism group had higher levels of lead in red blood cells and higher urinary levels of lead.[61] A stepwise, multiple linear regression analysis found a strong association of levels of Toxic Heavy Metals with variation in the degree of severity of autism for all the severity scales.[62] Cadmium (whole blood) and mercury (whole blood and RBC) were the most consistently significant variables.[63] The authors concluded that overall, children with autism have higher average levels of several Toxic Heavy Metals, and levels of several Toxic Heavy Metals are strongly associated with variations in the severity of autism.[64]

48. In sum, the heavy weight of the literature, as supported by meta-analyses, multiple studies employing varying methodologies and conducted in various countries, strongly supports a causal relationship between exposure to Toxic Heavy Metals and the development of ASD in children.

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

49. During the time that Defendants manufactured and sold Baby Foods in the United States, the weight of evidence showed that Defendants' Baby Foods exposed babies and children to unsafe levels of Toxic Heavy Metals. Defendants failed to disclose this risk to consumers through

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[58] *Id.*
[59] Adams, et al., *Toxicological Status of Children with Autism vs. Neurotypical Children and the Association with Autism Severity,* 151 BIOL. TRACE ELEM. RES 171-180 (2013), available at: https://pubmed.ncbi.nlm.nih.gov/23192845/.
[60] *Id.*
[61] *Id.*
[62] *Id.*
[63] *Id.*
[64] *Id.*

any means.

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

51. Indeed, independent testing performed in early 2019 demonstrated elevated amounts of such Toxic Heavy Metals in Baby Food products on the U.S. market,[65] and the HBBF Report further confirmed such contamination of Defendants' Baby Food.[66] And, as the Subcommittee found, Defendants continued to sell their Baby Food even after testing of both ingredients and finished products revealed the presence of substantial amounts of Toxic Heavy Metals.[67]

52. Moreover, the scientific literature on the dangers of Toxic Heavy Metals—particularly as it relates to adverse effects on the neurodevelopment of children—have been well known for decades. Defendants, as manufacturers of Baby Foods, are held to the standard of experts responsible for keeping abreast of the latest scientific developments related to the dangers of contaminants in their products. Defendants failed to take action in protecting vulnerable children from exposure to the Toxic Heavy Metals in their foods and, thus, subjected them to the risk of developing neurodevelopmental disorders such as ASD.

53. To be clear, Defendants are able to manufacture Baby Foods that do not pose such a dangerous risk to the health of infants and children by using alternative ingredients, not adding certain pre-mix minerals and vitamins high in Toxic Heavy Metals, or sampling their ingredients from other sources, as specifically acknowledged by Hain in its August 2019 presentation to the FDA: "Explore alternatives for Brown Rice ingredient to reduce risk."[68] At the very least, Defendants were under a duty to warn unsuspecting parents of the presence of Toxic Heavy Metals in

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[65] *See* Gardener, et al., *supra*.
[66] *See* HBBF Report, *supra*.
[67] *See, e.g.*, Subcommittee Report at 13-14.
[68] 2019 Hain & FDA Meeting at *10.

their Baby Foods. However, Defendants took no action, continued to sell their products with full knowledge of the risks posed by their Baby Foods, and misled consumers regarding the safety of their products, all to the harm of children.

A. Nurture

1. Nurture Sells Products Even After Testing Confirms Their High Toxic Heavy Metal Content and Regularly Uses Ingredients High in Toxic Heavy Metals in its Baby Food

54. According to internal company documents, Nurture sells products even after testing confirms that they are dangerously high in inorganic arsenic. Nurture sold one such product, Apple and Broccoli Puffs, despite tests results showing it contained 180 ppb inorganic arsenic.[69] An arsenic level of 180 ppb is high by all standards, but it is 80% higher than Nurture's own internal goal threshold of 100 ppb. Nurture routinely sold products that exceeded its internal standards. Twenty-nine other products that Nurture tested and sold registered over 100 ppb inorganic arsenic. In total, over 25% of the products that Nurture tested for inorganic arsenic, and sold, had inorganic arsenic levels above 100 ppb.[70]

55. Moreover, Nurture sold products that tested as high as 641 ppb lead—over six times higher than its internal limit of 100 ppb lead.[71] Nurture also sold five other products after they tested over 50 ppb lead.[72] Of the 206 finished products that Nurture tested for lead, 16 products registered over 20 ppb lead—exceeding the EU standard. And 39 products, or 18.9%, tested over 10 ppb lead.[73] It is not clear that even one of Nurture's baby food products registered at or below 1 ppb lead, which should be the upper limit for lead content according to health experts at Consumer Reports, the Environmental Defense Fund, and the American Academy of Pediatrics.[74] The average amount of inorganic arsenic in the baby

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[69] *See* Nurture, *Heavy Metal Test Results for Baby Food Products* (Dec. 18, 2019) ("Nurture Test Results"), available at: http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx).
[70] *Id*.
[71] *Id*.
[72] *Id*.
[73] *Id*.
[74] *See* Consumer Reports, *Consumer Reports letter to FDA on reducing heavy elements like arsenic, lead, and cadmium in fruit juices* (January 2019), available at:

foods that Nurture tested and sold was 59.54 ppb. That towers over existing and recommended standards, including FDA's and EPA's water limits of 10 ppb. At least 89 of Nurture's final products—over 78% of those products tested—tested at 9 ppb inorganic arsenic or above. For results under 9.54 ppb, Nurture did not differentiate—it marked them all as "<9.54." Because of this "less than" reporting format, there is no way to confirm if any of Nurture's products were free of inorganic arsenic. Nurture sold multi-grain cereal with 49 ppb cadmium;125 products that tested over 5 ppb, which is the EPA's limit for drinking water;[75] a finished baby food product that contained 10 ppb mercury; and two others that contained 9.8 and 7.3 ppb. A level of 10 ppb is five times more than the EPA's 2 ppb standard for drinking water. In total, Nurture sold 56 products that contained over 2 ppb mercury.

2. Nurture Willfully and Recklessly Disregards Internal and Regulatory Standards for Toxic Heavy Metals in is Baby Food.

56. Nurture created internal standards but did not follow them. Nurture describes these standards as "goal thresholds" that "are not used to make product disposition decisions and are not a pre-condition to product release."[76] Instead, its testing regime is limited to monitoring the supply chain as opposed to ensuring that babies are not exposed to Toxic Heavy Metals. Nurture's thresholds are not actually used to prevent products that contain high levels of toxic heavy metals from being sold.[77]

57. Nurture does not even claim to be testing for safety. In its letter response to the Subcommittee, Nurture stated: "our heavy metal testing is performed as part of our monitoring program and not as a condition of product release, all of the products that were tested were sold into

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https://advocacy.consumerreports.org/research/consumer-reports-letter-to-fda-on-reducing-heavy-elements-like-arsenic-lead-and-cadmium-in-fruit-juices/; ED, *FDA's outdated Lead Standards Put the Public's Health at Risk* (December, 9 2020), available at: https://www.edf.org/media/fdas-outdated-lead-standards-put-publics-health-risk; American Academy of Pediatrics, *Lead Exposure in Children* (2016), available at: https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/lead-exposure/Pages/Lead-Exposure-in-Children.aspx.

[75] *See* Nurture Test Results, *supra*.

[76] *Letter from Nurture, Inc. to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform* (Dec. 18, 2019) ("Letter from Nurture") at 3, available at: https://oversight.house.gov/sites/democrats.oversight.house.gov/files/10.pdf).

[77] *Id*. at 3-4.

commerce."[78] Nurture sells the products it tests, regardless of their toxic heavy metal content. In total, Nurture tested 113 final products and sold *every* product tested, regardless of how much inorganic arsenic or lead the product contained, and regardless of whether those metals exceeded its own internal standards. As a result of this policy of not testing for safety, Nurture released products containing as much as 641 ppb lead and 180 ppb inorganic arsenic.[79] Nurture sold 29 products that were above its internal arsenic limit of 100 ppb, including Apple & Broccoli Puffs that contained 180 ppb inorganic arsenic. Further, Nurture appears to have misled the Subcommittee about its testing standards. Nurture conveyed to the Subcommittee that after January of 2019, it had a goal threshold of 50 ppb for lead in all of its baby food products—infant formula, cereals, and wet foods.[80] However, after the date Nurture claims to have moved to a 50 ppb lead standard—January 2019—Nurture was still using a "Goal Threshold" of 100 ppb for 53 baby food products, as demonstrated by Nurture's internal tests.[81] Nurture blatantly lied to the Subcommittee about these results. And, Nurture has also ignored the only final standard that FDA has set. FDA set a 100 ppb inorganic arsenic limit for infant rice cereal. Rather than comply with that limit, Nurture set its internal standards 15% higher, at 115 ppb inorganic arsenic.[82]

B. Hain

1. Hain Regularly Fails to Test its Finished Baby Food and Sells Baby Food Notwithstanding High Content of Toxic Heavy Metals in Ingredients

58. Hain does not regularly test finished baby food products for inorganic arsenic content. It typically only tests ingredients. However, when Hain did test a small sample of finished product, it found 129 ppb inorganic arsenic.[83] In August 2019, Hain presented the results of its testing to the FDA in a closed-door meeting. During the presentation, Hain stated that its brown rice flour and vitamin premix contained high amounts of Toxic Heavy Metals, specifically noting that "preliminary

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[78] *Id*. at 4.
[79] Nurture Test Results, *supra*.
[80] Letter from Nurture at 1, 3.
[81] Nurture Test Results, *supra*.
[82] Letter from Nurture at 3.
[83] 2019 Hain & FDA Meeting at *9.

investigation indicates Vitamin/Mineral Pre-Mix may be a *major contributing factor*."[84] (emphasis added). Indeed, this was later confirmed by Hain's internal test results produced to the Subcommittee, which showed that its rice flour had tested at 309 ppb arsenic; vitamin pre-mix at 223 ppb arsenic, and raisin and wheat flour containing 200 ppb arsenic.[85] To be clear, Hain continued using these toxic ingredients even months *after* it had informed the FDA regarding its findings, as demonstrated by the later testing produced to the Subcommittee. The testing data also shows that Hain used at least 24 ingredients after testing found that they contained more than 100 ppb arsenic, its already-dangerously-high internal standard for most ingredients.[86]

59. Hain used six ingredients that tested above 200 ppb lead; 88 ingredients with lead levels at or over 20 ppb—the EU's standard for lead in infant formula;115 ingredients that registered at or over 15 ppb—EPA's action level for drinking water; and at least 27% of Hain ingredients tested at or over 5 ppb lead, FDA's standard for lead in bottled water.[87] None of the test results showed an ingredient below 1 ppb lead, the upper limit for lead content.[88] Hain used 14 ingredients that contained more than 100 ppb cadmium, including barley flour that registered at 260 ppb cadmium.[89] That is thirteen times the EU's upper limit on cadmium in baby food. Hain also tested and used 102 ingredients that registered at or above 20 ppb cadmium. Hain does not test its ingredients or finished products for mercury.

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[84] 2019 Hain & FDA Meeting at *6, 9, 10.
[85] Hain, *Raw Material Pre-Shipment Test Data History* (Dec. 11, 2019) ("Hain Test Results") at 00033, 00029, available at: https://oversight.house.gov/sites/democrats.oversight.house.gov/files/3_0.pdf).
[86] *See* Hain Testing Results at 00029-52.
[87] *See, id.*
[88] *See* Consumer Reports, *Consumer Reports letter to FDA on reducing heavy elements like arsenic, lead, and cadmium in fruit juices* (January 2019), available at: https://advocacy.consumerreports.org/research/consumer-reports-letter-to-fda-on-reducing-heavy-elements-like-arsenic-lead-and-cadmium-in-fruit-juices/; ED, *FDA's outdated Lead Standards Put the Public's Health at Risk* (December, 9 2020), available at: https://www.edf.org/media/fdas-outdated-lead-standards-put-publics-health-risk; American Academy of Pediatrics, *Lead Exposure in Children* (2016), available at: https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/lead-exposure/Pages/Lead-Exposure-in-Children.aspx.
[89] Hain Test Results at 00045.

2. Hain Set Dangerously High Internal Limits for Toxic Heavy Metals

60. Hain set an internal standard of 200 ppb arsenic for 12 ingredients, most of which were different kinds of flours. By setting this high internal standard, Hain justified accepting wheat flour and rice that contained 200 and 150 ppb arsenic.[90] Similarly, Hain set an internal limit of 200 ppb for lead in five ingredients—forty times higher than FDA's guidance for bottled water. By doing so, Hain justified accepting lentil flour with 110 ppb lead and quinoa flour with 120 ppb lead. These surpass every existing regulatory standard for lead.[91] Hain used four products that surpassed its internal toxic heavy metal limits. For example, it accepted cinnamon that contained 102 ppb cadmium, vitamin pre-mix that had 223 ppb arsenic and 353 ppb lead, and two rice flours that had 134 and 309 ppb arsenic.[92] Hain justified these variations by claiming that the "theoretical" final goods will not surpass its internal limits. In another example, Hain became aware that the vitamin pre-mix contained 223 ppb arsenic and 352 ppb lead.[93] And yet, despite having dangerously high levels of toxic heavy metals, Hain approved the use of this vitamin pre-mix based on a "theoretical" calculation of toxic heavy metals in the final good.[94]

61. To calculate the estimated quantity of lead and arsenic in the finished good, Hain considered the percentage of rice flour and vitamin pre-mix in the finished goods, and their projected amounts of arsenic and lead. Ultimately, Hain predicted that the finished good would have roughly 85 ppb arsenic and 25 ppb lead.[95] However, Hain never tested the finished product. Hain appears to have used this vitamin pre-mix with dangerously high levels of toxic heavy metals without ever confirming the finished good was actually safe to consume. Hain made this decision four months *after* it had made a secret presentation to FDA admitting that heavily tainted vitamin premix caused dangerous levels of arsenic in its finished products, which initially went undetected because Hain did

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[90] Hain, *Raw Material Pre-Shipment Test Data History* (Dec. 11, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/3_0.pdf).
[91] *Id*.
[92] *Id*.
[93] Hain, *Deviation Report, Vitamin Premix* (Nov. 26, 2019) at 000148, available at: https://oversight.house.gov/sites/democrats.oversight.house.gov/files/11_Redacted.pdf).
[94] *Id*.
[95] *Id*.

not test its finished products.[96] Hain made no effort to correct the problem.

C. Beech-Nut

1. Beech-Nut Does Not Test its Finished Baby Food for Toxic Heavy Metals and Uses Ingredients Containing High Amounts of the Metals

62. Beech-Nut only tested arsenic content in its ingredients, not its final product. Beech-Nut used ingredients containing as much as 913.4 ppb arsenic. Test results show that Beech-Nut used at least fourteen other ingredients containing over 300 ppb arsenic. And it used at least 45 ingredients containing over 100 ppb arsenic.[97] The six Beech-Nut ingredients with the highest arsenic levels—Amylase, BAN 800, Alpha Amylase, and Sebamyl 100—are all enzymes that Beech-Nut adds to its products. BAN 800 is an enzyme that reportedly "[i]ncreases crumb softness" in baked goods.[98] Amylase is an enzyme that is used in bread-making as an additive to improve the conversion of complex sugars into simple sugars that yeast is then able to feed on and produce alcohol and CO2. Moreover, Beech-Nut used ingredients in its baby foods that contained high lead levels. For instance, Beech-Nut used cinnamon that contained 886.9 ppb lead.[99] Beech-Nut tested and used 57 ingredients that contained over 20 ppb lead, the EU's standard for lead in infant formula; accepted 89 ingredients that tested at or over 15 ppb lead, EPA's action level for drinking water; and 483 ingredients that tested at or over 5 ppb lead, FDA's standard for lead in bottled water.[100] Beech-Nut used twenty ingredients registering over 100 ppb cadmium, including cinnamon containing 344.5 ppb cadmium.[101] That is more than 17 times higher than the EU's upper limit on cadmium in baby food. At least 105 ingredients that Beech-Nut tested and used in baby foods registered at or over 20 ppb cadmium—the EU's infant formula upper limit.[102] Beech-Nut does not test its ingredients or finished

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[96] 2019 Hain & FDA Meeting at *9-10.
[97] *See generally*, Beech-Nut, *Raw Material Heavy Metal Testing* (Dec. 6, 2019) ("Beech-Nut Tests"), available at: http://oversight.house.gov/sites/democrats.oversight.house.gov/files/4.xlsx).
[98] Novozymes, *Meet Consumer Demands with Enzymes that Support Organic Labeling* (May 2018) (online at www.novozymes.com/-/media/Project/Novozymes/Website/website/document-library/Advance-your-business/Baking/Baking-Product-Range-for-Organic-Production.pdf).
[99] Beech-Nut Tests.
[100] *Id*.
[101] *Id*.
[102] *Id*.

products for mercury.

2. Beech-Nut Set Internal Limits for Toxic Heavy Metals Far Above Regulatory Standards and Regularly Violated Its Own Limits

63. Beech-Nut has set an internal specification limit of 3,000 ppb inorganic arsenic for certain ingredients, including vitamin mix.[103] As a result of adopting this staggering and irresponsibly high internal standard, Beech-Nut has used ingredients containing 710.9, 465.2, and 401.4 ppb arsenic.[104] Beech-Nut also set internal guidelines of 3,000 ppb for cadmium and 5,000 ppb for lead for certain ingredients.[105] These far surpass any existing regulatory standard in existence and Toxic Heavy Metal levels for any other baby food manufacturer that responded to the Subcommittee investigation. Beech-Nut sold eleven products that surpassed its own internal cadmium limits. By doing so, Beech-Nut accepted dehydrated potato containing 119.6, 143.5, and 148.4 ppb cadmium, far surpassing its own internal limit of 90 ppb for that ingredient.[106]

64. Beech-Nut's explanation of why it accepted products over its own internal limits was that it did so "rarely" and the ingredients were "generally restricted to a 20% variance of BNN's allowable limits…."[107] However, as the cadmium examples show, Beech-Nut accepted certain ingredients in spite of its own testing results which showed that they contained over 20% more cadmium than their already-high internal limit. Beech-Nut's internal limit for cadmium in dehydrated potato appears to be 90 ppb. A 20% variance would permit Beech-Nut to accept dehydrated potato containing up to 108 ppb cadmium. Nevertheless, Beech-Nut accepted three shipments of dehydrated potato containing cadmium in excess of its 20% variance allowance.[108] Beech-Nut failed to offer any explanation to the Subcommittee.

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[103] *Id*.
[104] *Id*.
[105] *Id*.
[106] *Id*.
[107] *Letter from the President and Chief Executive Officer of Beech-Nut Nutrition Company to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform* ("Letter from Beech-Nut") (Dec. 6, 2019) at 4, available at: https://oversight.house.gov/sites/democrats.oversight.house.gov/files/6_0.pdf).
[108] *See* Beech Nut Test ("dehydrated potato).

D. Gerber

65. Test results for conventional rice flour revealed that Gerber routinely uses flour with over 90 ppb inorganic arsenic.[109] Gerber used five batches of rice flour that had 98 ppb inorganic arsenic, and 67 batches that contained more than 90 ppb.[110] The results for Gerber sweet potatoes and juices demonstrated its willingness to use ingredients that contained dangerous lead levels. Gerber used an ingredient, conventional sweet potatoes, with 48 ppb lead and twelve other batches of sweet potato that tested over 20 ppb for lead, the EU's lenient upper standard.[111] The average amount of lead in Gerber's tested juice concentrates was 11.2 ppb—more than FDA's limit for lead in bottled water. Over 83% of the juice concentrates tested showed greater than 1 ppb lead, which is Consumer Reports' recommended limit for fruit juices.[112] Gerber does not test all its ingredients for cadmium. Of those it does test, it accepts ingredients with high levels of cadmium. Gerber used multiple batches of carrots containing as much as 87 ppb cadmium, and 75% of the carrots Gerber used had more than 5 ppb cadmium—the EPA's drinking water standard.[113] Gerber only tests certain ingredients for mercury. Of the test results Gerber presented to the Subcommittee, it only tested carrots, sweet potatoes, and lemon juice concentrate.[114]

E. Plum and Sprout

66. As discussed above, although Plum and Sprout did not cooperate with the Subcommittee's investigation, the independent test results from HBBF's Report confirm that these two Defendants sold Baby Foods with substantial levels of Toxic Heavy Metals, and accordingly knew or should have known about the risk presented by such metals.[115] As noted by the Subcommittee, the fact that these companies refused to produce testing results, internal company documents, or specific testing standards, strongly suggests that these companies "might be obscuring

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[109] Gerber, *Gerber Products Company Test Results* (Dec. 9, 2019) ("Gerber Tests"), available at: https://oversight.house.gov/sites/democrats.oversight.house.gov/files/5_0.pdf).
[110] *Id*. at *3-4, 7.
[111] *Id*. at *16,
[112] *Id*. at *9-11.
[113] *Id*. at *15.
[114] *Id*. at *15, 16, 18, 22-24.
[115] *See* HBBF Report at 19-28.

the presence of even higher levels of toxic heavy metals in their baby food products than their competitors' products."[116]

67. Indeed, even the limited testing conducted by HBBF demonstrates that Plum and Sprout also acted out of callous disregard for human—specifically children's—health by selling Baby Foods contaminated with substantial amounts of Toxic Heavy Metals. As the Subcommittee noted, "[w]hether due to evasion or negligence, Sprout's failure to respond raises serious concerns about the presence of toxic heavy metals in its baby foods, as even limited independent testing has revealed the presence of toxic heavy metals in its products."[117] Indeed, the HBBF testing reports that Sprout's "organic Quinoa Puffs Baby Cereal Snack—Apple Kale contains 107 ppb arsenic, 47 ppb inorganic arsenic, 39.3 ppb lead, 41.5 cadmium, and 1.31 ppb mercury; "Prunes Organic Baby Food starting solids" contains 6.1 ppb lead; "Carrot Apple Mango Organic Baby Food" aimed at 6+ months contains 2.1 ppb lead, 15.1 ppb cadmium; and "Garden Vegetables Brown Rice with Turkey" for 8+ months contains 7.2 ppb arsenic, 1.6 ppb lead, 2.5 ppb cadmium, among other foods with similarly high contents of these Toxic Heavy Metals.[118]

68. Similarly, Plum refused to produce testing standards and the Subcommittee noted that Plum "has hidden its policies and the actual level of toxic heavy metals in its products."[119] The self-serving spreadsheet produced by Plum wherein it declares, without any data, that its products "meet criteria" (without identifying which criteria), poses more questions than it answers.[120] Indeed, Plum has admitted that that it does not have a "specific threshold" established for the powerful neurotoxin mercury because "no high-risk ingredients are used."[121] As well as evincing Plum's reckless disregard for the safety of children by refusing to establish a threshold for a toxin as dangerous as mercury, the statement is also outright false. The limited testing performed by HBBF reveals that

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[116] Subcommittee Report at 43.
[117] Subcommittee Report at 46.
[118] HBBF Report at 26, 23, 25.
[119] Subcommittee Report at 44.
[120] Campbell, *Product Heavy Metal Test Results* (Dec. 11, 2019) ("Plum Tests"), available at: https://oversight.house.gov/sites/democrats.oversight.house.gov/files/12.pdf).
[121] Plum Tests at 00046.

Plum's "Little Teethers Organic Multigrain Teething Wafers—Banana with Pumpkin" intended for crawling babies contains 0.726 ppb mercury, and Plum's "Apple, Raisin, & Quinoa Organic Baby Food" contain 0.145 ppb mercury, flatly contradicting Plum's assertion that none of its products contain mercury.[122]

69. Although discovery will flesh out the full extent to which Plum and Sprout's Baby Foods are tainted with Toxic Heavy Metals, it is abundantly clear that these Defendants are no less culpable in its wrongdoing than its competitors who provided data to the Subcommittee.

VI. Exemplary / Punitive Damages Allegations

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

71. Defendants were fully aware of the safety risks of Baby Foods, particularly the dangerous potential of their Baby Foods given the high content of Toxic Heavy Metals that have all been associated with neurodevelopmental disorders in children. Nonetheless, Defendants deliberately crafted their label, marketing, and promotion to mislead consumers. Indeed, Defendants repeatedly market their Baby Foods as safe for consumption and go so far as claiming that they adhere to "the strictest standards in the world"; and provide "baby's food full of nutrition while meeting standards strict enough for tiny tummies." In actual fact, as discussed above, Defendants routinely sold Baby Foods containing astronomical amounts of Toxic Heavy Metals, regularly flouted their own internal limits of Toxic Heavy Metals in Baby Foods and failed to disclose to consumers that their products contained such dangerous contaminants.

72. This was not done by accident or through some justifiable negligence. Rather, Defendants knew they could profit by convincing consumers that their Baby Foods were harmless to humans, and that full disclosure of the true risks of the Toxic Heavy Metals present in the Baby Foods would limit the amount of money Defendants would make selling the products. Defendants'

[122] HBBF Report at 27, 25.

object was accomplished not only through a misleading label, but through a comprehensive scheme of selective misleading research and testing, failure to test, false advertising, and deceptive omissions as more fully alleged throughout this pleading. Parents were denied the right to make an informed decision about whether to purchase and Defendants' Baby Food for their children, knowing the full risks attendant to that use. Such conduct was done with conscious disregard of Plaintiffs' rights.

73. Accordingly, Plaintiffs request punitive damages against the Manufacturer Defendants for the harms caused to Plaintiffs.

PLAINTIFF-SPECIFIC ALLEGATIONS

74. Plaintiffs each consumed Baby Foods manufactured and sold by Plum, Hain, Nurture, Beech-Nut, Gerber, and Sprout for approximately over 1 year and 1 year, respectively. Plaintiffs consumed Defendants' Baby Foods during overlapping time periods and within the same household.

75. Upon information and belief, the baby foods consumed by Plaintiffs were contaminated with substantial quantities of Toxic Heavy Metals, exceeding that of existing regulatory limits.

76. As a direct and proximate result of consuming Defendants' Baby Foods, Plaintiffs were diagnosed with ASD.

77. Based on prevailing scientific evidence, exposure to the Toxic Heavy Metals at the levels contained in Defendants' Baby Foods can cause ASD in humans.

78. Had any Defendant warned Plaintiffs' parents that Defendants' Baby Foods could lead to exposure to Toxic Heavy Metals or, in turn, ASD, Plaintiffs would not have consumed the Baby Foods.

79. Plaintiffs allege that as a direct and proximate result of Plaintiffs' consumption of Baby Foods supplied and distributed by Defendants, Plaintiffs suffered significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to ASD and other *sequelae*.

CAUSES OF ACTION

COUNT I: STRICT PRODUCTS LIABILITY – FAILURE TO WARN

80. Plaintiffs incorporate by reference each allegation set forth in preceding paragraphs as

if fully stated herein.

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

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

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

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

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

86. Even though Defendants knew or should have known that Baby Foods posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the products. The dangerous propensities of their products and the neurotoxic

characteristic of Toxic Heavy Metals contained in Defendants' Baby Foods, as described above, were known to Defendants, or scientifically knowable to Defendants through appropriate research and testing by known methods, at the time they distributed, supplied or sold the product, and were not known to end users and consumers, such as the Plaintiffs. The product warnings for Baby Foods in effect during the time period Plaintiffs consumed Baby Foods were vague, incomplete or otherwise inadequate, both substantively and graphically, to alert consumers to the severe health risks associated with Baby Foods consumption.

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

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

89. Plaintiffs were exposed to Defendants' Baby Foods without knowledge of their dangerous characteristics.

90. At all relevant times, Plaintiffs were exposed to Defendants' Baby Foods while using them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

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

92. Defendants knew or should have known that the information disseminated with their

Baby Foods were inadequate, failed to communicate adequate information on the dangers consumption, and failed to communicate warnings and instructions that were appropriate and adequate to render the products safe for their ordinary, intended and reasonably foreseeable uses.

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

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

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

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

97. The Defendants' lack of adequate warnings and instructions accompanying their Baby

Foods were a substantial factor in causing Plaintiffs' injuries.

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

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

COUNT II: STRICT PRODUCTS LIABILITY – DESIGN DEFECT

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

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

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

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

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

105. At all relevant times, the Baby Food products consumed by Plaintiffs were expected to and did reach Plaintiffs without a substantial change in its condition as manufactured, handled,

distributed, and sold by Defendants.

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

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

a. When placed in the stream of commerce, Defendants' Baby Food products were unreasonably dangerous in that they were hazardous and posed a grave risk of neurodevelopmental disorders—specifically ASD—when used in a reasonably anticipated manner due to the substantial quantities of Toxic Heavy Metals in the Baby Foods;

b. When placed in the stream of commerce, Defendants' Baby Food products contained unreasonably dangerous design defects and were not reasonably safe when used in a reasonably anticipated or intended manner;

c. Defendants did not sufficiently test, investigate, or study their Baby Food products;

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

e. Defendants knew or should have known at the time of marketing Baby Food products that exposure to their Baby Food products could result in neurodevelopmental disorders—specifically ASD—in children.

f. Defendants did not conduct adequate post-marketing surveillance of their Baby Food products; and

g. Defendants could have employed safer alternative designs and formulations.

108. Plaintiffs consumed Defendants' Baby Food products in an intended or reasonably

foreseeable manner without knowledge of their dangerous characteristics.

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

110. At the time the Baby Food products left Defendants' control, there was a practical, technically feasible and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Baby Foods, as for example, demonstrated by Hain's presentation to the FDA wherein Hain acknowledges the risk posed by specific ingredients in its Baby Foods.

111. Defendants have intentionally and recklessly defectively designed the Baby Foods with wanton and willful disregard for the rights and health of the Plaintiffs, and with malice, placing their economic interests above the health and safety of the Plaintiffs.

112. The design defects in Defendants' Baby Foods were substantial factors in causing Plaintiffs' injuries.

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

WHEREFORE, Plaintiffs respectfully request this Court to enter judgment in Plaintiffs' favor for damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT III: STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

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

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

116. At all relevant times, the Baby Foods consumed by Plaintiffs were expected to and did

reach Plaintiffs without a substantial change in its condition as manufactured, handled, distributed, and sold by Defendants.

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

118. The Baby Foods consumed by Plaintiffs were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design and manufacturing specifications and/or such design and manufacture posed an unreasonable risk of harm to Plaintiffs.

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

120. The Baby Foods create risks to the health and safety of babies that are far more significant and devastating than the risks posed by other baby food products, and which far outweigh the utility of the Baby Foods products because of Defendants' manufacturing defects, which included but were not limited to:

a. Failure to adequately inspect/test the Baby Foods during the manufacturing process;

b. Failure to implement procedures that would reduce or eliminate the levels of Toxic Heavy Metals in Baby Foods;

c. Failure to avoid using ingredients free from, or which contain far less, Toxic Heavy Metals to manufacture Baby Foods.

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

122. The manufacturing defects in Defendants' Baby Foods were substantial factors in causing Plaintiffs' injuries.

123. As a direct and proximate result of the Defendants' defective manufacture of the Baby Foods, Plaintiffs have been injured, sustained severe and permanent pain, suffering, disability,

impairment, loss of enjoyment of life, economic loss and damages including, but not limited to medical expenses, lost income, and other damages.

WHEREFORE, Plaintiffs respectfully request this Court to enter judgment in Plaintiffs' favor for damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT IV: NEGLIGENCE – FAILURE TO WARN

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

125. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and promoting Baby Foods. Defendants knew or by the exercise of reasonable care should have known that their Baby Foods are not accompanied with adequate warnings concerning the dangerous characteristics of Baby Foods and Toxic Heavy Metals. These actions were under the ultimate control and supervision of Defendants.

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

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

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

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

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

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

132. At all relevant times, Plaintiffs were exposed to excessive levels of Toxic Heavy Metals through consumption of Toxic Heavy Metals while using them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

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

134. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs to avoid using the product. Instead, Defendants disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of and/or exposure to Baby Foods; continued to

aggressively promote the efficacy of their products, even after they knew or should have known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of consuming Baby Foods.

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

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

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

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

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

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

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

COUNT V: NEGLIGENT PRODUCT DESIGN

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

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

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

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

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

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

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

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

d. Defendants did not sufficiently test, investigate, or study their Baby Foods and, specifically, the content of Toxic Heavy Metals in the ingredients used to

manufacture the foods and/or the finished products;

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

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

g. Defendants knew or should have known at the time of marketing Baby Foods that exposure to Toxic Heavy Metals contained in the Baby Foods could result in neurodevelopmental disorders—specifically ASD—and other severe illnesses and injuries;

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

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

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

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

149. Plaintiffs were harmed directly and proximately by the Defendants' failure to use reasonable care in the design of their Baby Foods. Such harm includes significant exposure to a Toxic Heavy Metals, which can cause or contribute to the development of neurodevelopmental disorders such as ASD.

150. Defendants' defective design of Baby Foods was willful, wanton, malicious, and conducted with reckless disregard for the health and safety of consumers of the Baby Foods,

including Plaintiffs.

151. The defects in Defendants' Baby Foods were substantial factors in causing Plaintiffs' injuries.

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

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

COUNT VI: NEGLIGENT MANUFACTURING

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

155. At all relevant times, the Defendants manufactured, tested, marketed, sold, and distributed the Baby Foods that Plaintiffs consumed.

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

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

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

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

a. Failure to adequately inspect/test the Baby Foods during the manufacturing process;

b. Failure to implement procedures that would reduce or eliminate levels of Toxic

Heavy Metals in Baby Foods; and

c. Failure to avoid using ingredients free from, or which contain far less, Toxic Heavy Metals to manufacture Baby Foods.

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

161. Plaintiffs were harmed directly and proximately by the Defendants' failure to use reasonable care in the manufacture of their Baby Foods. Such harm includes significant exposure to a Toxic Heavy Metals, which can cause or contribute the development of neurodevelopmental disorder such as ASD.

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

163. The defects in Defendants' Baby Foods were substantial factors in causing Plaintiffs' injuries.

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

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

COUNT VII: NEGLIGENT MISREPRESENTATION

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

167. At all relevant times, Defendants designed, manufactured, tested (or not), packaged, labeled, marketed, advertised, promoted, supplied, distributed, sold and/or otherwise placed Baby Foods into the stream of commerce, and therefore owed a duty of reasonable care to avoid causing

harm to those that consumed Baby Foods, such as Plaintiffs.

168. Defendants were negligent, reckless, and careless and owed a duty to Plaintiffs to make accurate and truthful representations regarding Baby Foods, Defendants breached their duty, thereby causing Plaintiffs to suffer harm.

169. Defendants represented to Plaintiffs via the media, advertising, website, social media, packaging, and promotions, among other misrepresentations described herein that:

170. Baby Foods were both safe and effective for the lifetime of the product, when in fact, the foods contain unsafe levels of Toxic Heavy Metals far in excess of regulatory standards; and

171. Consumption of Baby Foods would not expose babies to any harmful ingredients; and

172. Baby Foods were safe for their intended use when, in fact, Defendants knew or should have known the products were not safe for their intended purpose.

173. These representations were false. Because of the presence and/or unsafe levels of Toxic Heavy Metals in Baby Foods, the products presented an unacceptable risk of causing neurodevelopmental disorders, specifically ASD.

174. Defendants knew or should have known these representations were false and negligently made them without regard for their truth.

175. Defendants had a duty to accurately provide this information to Plaintiffs. In concealing this information from Plaintiffs, Defendants breached their duty. Defendants also gained financially from, and as a result of their breach.

176. Defendants intended for Plaintiffs to rely on these representations.

177. Each of these misrepresentations were material at the time they were made. In particular, each of the misrepresentations concerned material facts that were essential to the analysis undertaken by Plaintiffs as to whether to purchase or consume Baby Foods.

178. Defendants have yet to correct these misrepresentations about Baby Foods.

179. Plaintiffs reasonably relied on these representations and were harmed as described herein. Plaintiffs' reliance on Defendants' representation was a substantial factor in causing Plaintiffs' harms. Had Defendants told Plaintiffs the truth about the safety and composition of Baby Foods, Plaintiffs would not have consumed or purchased them.

180. Defendants' acts and omissions as described herein were committed in reckless disregard of Plaintiffs' rights, interests, and well-being to enrich Defendants.

181. Plaintiffs were injured as a direct and proximate result of Defendants' negligent misrepresentations regarding Baby Foods as described herein.

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

JURY TRIAL DEMAND

183. Plaintiffs demand a trial by jury on all the triable issues within this pleading.

PRAYER FOR RELIEF

184. WHEREFORE, Plaintiffs request the Court to enter judgment in Plaintiffs' favor and against the Defendants for:

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

b. exemplary and punitive damages sufficient to punish and deter the Defendants and others from future wrongful practices;

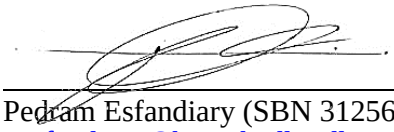
c. pre-judgment and post-judgment interest;

d. costs including reasonable attorneys' fees, court costs, and other litigation expenses; and

e. any other relief the Court may deem just and proper.

Dated: March 5, 2021

BAUM HEDLUND ARISTEI & GOLDMAN, P.C.



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