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**Pro Hac Vice admission to be sought*

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

Mariah Schmucker and Kayla
McGowan, individually and on behalf of
all others similarly situation,

Plaintiffs,

v.

Schwabe North America, Inc. and
Nature's Way Brands, LLC,

Defendants.

Case No. 2:22-at-189

CLASS ACTION COMPLAINT FOR:

(1) NEGLIGENT
MISREPRESENTATION;
(2) VIOLATIONS OF THE
CALIFORNIA CONSUMER LEGAL
REMEDIES ACT;
(3) VIOLATIONS OF THE
CALIFORNIA FALSE ADVERTISING
LAW;
(4) VIOLATIONS OF THE
CALIFORNIA UNFAIR COMPETITION
LAW;
(5) BREACH OF EXPRESS
WARRANTY;
(6) BREACH OF IMPLIED
WARRANTY OF
MERCHANTABILITY;
(7) UNJUST ENRICHMENT;
(8) FRAUDULENT
MISREPRESENTATION; AND
(9) FRAUD BY OMISSION

[Demand for Jury Trial]

1. Plaintiffs Mariah Schmucker and Kayla McGowan (collectively, “**Plaintiffs**”), individually and on behalf of all others similarly situated, by and through her undersigned attorneys, bring this Class Action Complaint against Defendants Schwabe North America, Inc., and Nature’s Way Brands, LLC (collectively, “**Defendants**”), for their negligent, reckless, and/or intentional practice of mismarketing their Nature’s Way Prenatal Vitamins (“**Products**” or “**Prenatal Vitamins**”)¹ sold throughout the United States. Defendants’ mismarketing is twofold. First, Defendants fail to disclose the presence, or risk, of dangerous substances in the Prenatal Vitamins, including heavy metals. Second, Defendants misrepresent the quantity of ingredients in their Prenatal Vitamins, including the amount of Folic Acid. Plaintiff seeks both injunctive and monetary relief on behalf of the proposed Class (as defined herein), including requiring full and accurate disclosure of all dangerous substances, ingredients, and nutrients in its marketing, advertising, and labeling, and restoring monies to the members of the proposed Class. Plaintiffs allege the following based upon personal knowledge as well as investigation by their counsel, and as to all other matters, upon information and belief, Plaintiffs believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE CASE

I. Introduction

2. The significance of prenatal health is underscored by the words of Ian Donald, the obstetrician who developed ultrasound diagnostics in Europe during the twentieth century, when

¹ “**Product**” or “**Prenatal Vitamin**” includes any prenatal product Defendants refer to as a supplement, multivitamin, multimineral, prenatal, or gummy, and collectively refers to any omissions regarding the risk of exposure to heavy metals and/or the presence of heavy metals, and/or misrepresentations regarding quality control, and/or misrepresentations regarding the quantity or amount of the ingredients, including folic acid, as stated on the label, and/or misrepresentations regarding the quantity or amount of the ingredients, including folic acid, in the formulation of the following Nature’s Way products: Nature’s Way Alive!® Complete Prenatal Multi-Vitamin; Nature’s Way Prenatal Multi-Vitamin and Multi-Mineral; Nature’s Way Alive!® Prenatal Gummy; and Nature’s Way Completia® Prenatal Multi-Vitamin. Discovery may reveal additional products that also contain levels of Heavy Metals and reflect an inaccurate amount of Folic Acid than the amount depicted on the product label. Plaintiffs reserves their right to include any such products in this action.

1 he stated: “The first 38 weeks of life spent in the allegedly protected environment of the amniotic
2 sac are medically more eventful and more fraught with danger than the next 38 years in the life
3 span of most human individuals.”²

4 3. The importance of prenatal health has not gone unnoticed to expectant mothers or
5 women who may become pregnant. And the prenatal vitamin market is capitalizing on the
6 increased awareness.

7 4. The North America Prenatal Vitamin market was valued at an estimated 200.47
8 million U.S. dollars (“USD”) in the United States in 2020, and the market is expected to increase
9 by almost USD 100 million in the next five years, reaching a market value of USD 293.6 million,
10 by 2025.³

11 5. The incredible rise in consumer demand for prenatal vitamins is due to “[t]he
12 growing health awareness among pregnant women regarding proper diet.”⁴ Following a healthy
13 diet and taking a nutritious prenatal vitamin are important to supporting the growth of the fetus
14 and the mother’s overall health.⁵

15 6. The surge in sales of prenatal vitamins has also increased due to promotional
16 initiatives by the market vendors, like Defendants.⁶ “Prenatal vitamin supplements are gaining
17 popularity in the market due to aggressive promotion and enhanced sales channels increasing
18 accessibility to the consumers.”⁷

19 _____
20 ² Stephen J. Genuis, Rebecca A. Genuis, "Preconception Care: A New Standard of Care within
21 Maternal Health Services", *BioMed Research International*, vol. 2016, Article
22 ID 6150976, 30 pages, 2016. Available at <https://doi.org/10.1155/2016/6150976> (last accessed
23 July 30, 2021).

24 ³ North America Prenatal Vitamins Supplement Market, Market Data Forecast, available at
25 <https://www.marketdataforecast.com/market-reports/na-prenatal-vitamins-supplements-market>
26 (last accessed January 3, 2022) (“Vitamins Supplement Market Data Forecast”).

27 ⁴ *Id.*

28 ⁵ The American College of Obstetricians and Gynecologists, “Nutrition During Pregnancy FAQs,”
updated March 2021, available at <https://www.acog.org/womens-health/faqs/nutrition-during-pregnancy> (last accessed January 3, 2022) (“Nutrition During Pregnancy”).

⁶ *Vitamins Supplement Market Data Forecast, supra.*

⁷ *Id.*

7. Among the North America Prenatal Vitamins Supplements market, Folic Acid supplements held the largest share of its market segment, a segment which also includes Iron, Calcium, and Essential Fatty Acids.⁸

8. Folic Acid, a synthetic form of Folate, the naturally occurring form of vitamin B9, plays a critical role in supporting prenatal health.⁹ Leading up to and during pregnancy, Folic Acid helps prevent major birth defects of the brain and spine called neural tube defects (“NTD”), such as spina bifida.¹⁰ Due to the significance of Folic Acid during pregnancy, consumers, like Plaintiffs, read the Product label to ensure its ingredients, including Folic Acid, provide the appropriate nutrition to support their prenatal health.¹¹

9. Given the importance of prenatal vitamins to the mother’s and baby’s health, women like Plaintiff who are pregnant or who may become pregnant trust Defendants to sell prenatal vitamins that are natural, nutritious, and nurturing of a healthy pregnancy, that are free from harmful toxins, contaminants, and chemicals, such as **Heavy Metals**,¹² and that contain the amount of ingredients, like Folic Acid, that are reflected on the Product label.

10. However, unbeknownst to women like Plaintiffs, Defendants’ Prenatal Vitamins contain, or risk containing, dangerous substances in the form of Heavy Metals and contain, or risk containing, less Folic Acid than the amount represented on the Product label.

⁸ *Id.*

⁹ Healthline, “Folic Acid vs. Folate – What’s the Difference?” *available at* <https://www.healthline.com/nutrition/folic-acid-vs-folate#folate> (last accessed October 18, 2021).

¹⁰ *Nutrition During Pregnancy, supra.*

¹¹ In accordance with the Federal Rule for New Supplement Facts Labeling, companies like Defendants now state on their label a “[Percentage] Daily Value for the total amount of Folate in a product, and if any of the total Folate comes from Folic Acid, that amount of Folic Acid is listed in mcg in parentheses.” *See* U.S. Food and Drug Administration, “Folate and Folic Acid on the Nutrition and Supplement Facts Labels,” June 29, 2020, *available at* <https://www.fda.gov/food/new-nutrition-facts-label/folate-and-folic-acid-nutrition-and-supplement-facts-labels> (last accessed January 3, 2022).

¹² As used herein, “**Heavy Metals**” is collectively defined as Arsenic, Cadmium, Lead, and Mercury.

1 **II. Heavy Metals**

2 11. Defendants fail to disclose the presence, or risk, of Heavy Metals in their Products,
3 with the exception of one Product label which states that it “does not contain harmful mercury
4 levels” but does not state the level of Mercury the Product contains.

5 12. Consumers like Plaintiffs expect the prenatal vitamins they consume to be free from
6 Heavy Metals.

7 13. Consumers like Plaintiffs lack the scientific knowledge necessary to determine
8 whether the Defendants’ Products do in fact contain Heavy Metals or to know or ascertain the true
9 nature of the ingredients and quality of the Products. Reasonable consumers therefore must and do
10 rely on Defendants to honestly report what their Products contain, especially as it pertains to the
11 disclosure of Heavy Metals.

12 14. Exposure to Heavy Metals has significant and dangerous health consequences. A
13 recent report by the U.S. House of Representatives’ Subcommittee on Economic and Consumer
14 Policy, Committee on Oversight and Reform (“**Congressional Committee Report**”) highlighted
15 the risk of including Heavy Metals in baby food, spurred by the knowledge that “[e]ven low levels
16 of exposure can cause serious and often irreversible damage to brain development.”¹³

17 15. The risk of harm to babies exposed to Heavy Metals starts even before birth, when
18 the baby is developing in-utero. If an expectant mother is taking a vitamin with Heavy Metals,
19 those Heavy Metals will cross the placenta, contaminating the child’s development and causing
20
21

22 ¹³U.S. House of Representatives, Committee on Oversight and Reform, Subcommittee on
23 Economic and Consumer Policy, Staff Report, Baby Foods Are Tainted with Dangerous Levels of
24 Arsenic, Lead, Cadmium, and Mercury, February 4, 2021, *available at*
25 [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-02-04%20ECP%20](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-02-04%20ECP%20Baby%20Food%20Staff%20Report.pdf)
26 [Baby%20Food%20Staff%20Report.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-02-04%20ECP%20Baby%20Food%20Staff%20Report.pdf) (last accessed January 3, 2022) (“Congressional
27 Committee Report”). *See also* U.S. House of Representatives, Committee on Oversight and
28 Reform, Subcommittee on Economic and Consumer Policy, Staff Report, “New Disclosures Show
Dangerous Levels of Toxic Heavy Metals in Even More Baby Foods,” September 29, 2021,
available at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/ECP%20](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/ECP%20Second%20Baby%20Food%20Report%209.29.21%20FINAL.pdf)
[Second%20Baby%20Food%20Report%209.29.21%20FINAL.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/ECP%20Second%20Baby%20Food%20Report%209.29.21%20FINAL.pdf) (last accessed January 9,
2022).

adverse health effects.¹⁴ “The toxicological effects of heavy metals could alter the physiological changes during pregnancy, the critical phase of fetal cell division and differentiation.”¹⁵ Chronic low dose and consistent exposure to Heavy Metal toxicity to an infant during pregnancy can result in preterm delivery, stillbirth, or miscarriage.¹⁶

16. Exposure to Heavy Metals during pregnancy may also lead to negative health outcomes in early childhood and beyond.¹⁷ After birth, the Heavy Metal exposure can result in the child developing behavioral and neurocognitive conditions including autism or Attention-Deficit/Hyperactivity Disorder (“**ADHD**”).¹⁸

17. Provided the risk of harm to a child in-utero from Heavy Metal exposure, Defendants know that their customers trust the quality of their Products and that their customers expect Defendants’ Products to be free of Heavy Metals. Defendants also know that certain consumers seek out and wish to purchase prenatal vitamins that possess high quality ingredients free of toxins, contaminants, or chemicals. Additionally, Defendants know that these consumers will pay the price premium for prenatal vitamins they believe possess these qualities.

18. As such, Defendants’ promises, warranties, pricing, statements, claims, packaging, labeling, Marketing, and advertising (hereinafter collectively referred to as “**Marketing**” or “**Claims**”) center on representations that are intended to, and do, convey to consumers that the Prenatal Vitamins, including the Prenatal Vitamins, possess certain qualities and characteristics that support a mother’s and developing baby’s health.

¹⁴ Wai, K. M., Mar, O., Kosaka, S., Umemura, M., & Watanabe, C. (2017). Prenatal Heavy Metal Exposure and Adverse Birth Outcomes in Myanmar: A Birth-Cohort Study. *International journal of environmental research and public health*, 14(11), 1339. Available at <https://doi.org/10.3390/ijerph14111339> (last accessed January 3, 2022).

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ ADHD and Autism Associated with In-Utero Heavy Metals and Essential Minerals, NeuroscienceNews.com, April 9, 2021, available at <https://neurosciencenews.com/asd-adhd-heavy-metals-18207/> (last accessed January 3, 2022).

1 19. No reasonable consumer seeing Defendants' Marketing would expect the Prenatal
2 Vitamins to contain or risk containing Heavy Metals. Furthermore, reasonable consumers, like
3 Plaintiffs, would consider the mere inclusion, or risk of inclusion, of Heavy Metals a material fact
4 when shopping for a nutritious prenatal vitamin.

5 20. Defendants intended for consumers to rely on their Marketing, and reasonable
6 consumers did in fact so rely. However, Defendants' Marketing is deceptive, misleading, unfair,
7 and/or false because, among other things, the Prenatal Vitamins include or risk including
8 undisclosed Heavy Metals.

9 21. With the exception of Nature's Way Alive!® Complete Prenatal Multi-Vitamin,
10 which acknowledges that the product "does not contain harmful mercury levels," yet does not state
11 the level of Mercury the Product contains, Defendants' Prenatal Vitamins do not have a disclaimer
12 regarding the presence of Heavy Metals that would inform consumers that the Products contain,
13 or risk containing, Heavy Metals, and/or that Heavy Metals can accumulate over time in a
14 developing child's body to the point where negative health outcomes can occur.

15 **III. Folic Acid**

16 22. Defendants misrepresent the amount of Folic Acid in their Prenatal Vitamins.

17 23. Consumers like Plaintiffs expect that when a prenatal vitamin states that it contains
18 a certain amount of a nutrient, especially one as important to prenatal health as Folic Acid, that the
19 prenatal vitamin actually contains the amount stated on the Product label.

20 24. Consumers lack the scientific knowledge necessary to determine whether the
21 Defendants' Products do in fact contain the actual amount of Folic Acid that is stated on the label,
22 or to know or ascertain the true amount of Folic Acid in the Products. Reasonable consumers
23 therefore must and do rely on Defendants to honestly report the amount of Folic Acid their
24 Products contain.

25 25. Folic Acid is critical to the health of women who are pregnant or may become
26 pregnant. Folic Acid helps prevent babies from developing NTDs, including spina bifida.¹⁹

27 _____
28 ¹⁹ U.S. Department of Health & Human Services, Office on Women's Health, "Folic Acid," last
updated April 1, 2019, available at <https://www.womenshealth.gov/a-z-topics/folic>

26. Given the critical role of Folic Acid to the health of women like Plaintiffs who are pregnant or may become pregnant, Defendants know that their customers trust the quality of their Products and that they expect Defendants' Products to provide the amount of Folic Acid that is presented on their Products' labels.

27. As such, Defendants' Marketing centers on representations that are intended to, and do, represent to consumers that their Prenatal Vitamins contain an amount of Folic Acid that justify a consumer paying a price premium for their Products.

28. No reasonable consumer seeing Defendants' Marketing would expect the Prenatal Vitamins to contain, or have the risk of containing, less Folic Acid than the amount represented on the label.

29. Reasonable consumers would consider the risk of deficiency in the amount of Folic Acid a material fact when considering what prenatal vitamins to purchase.

30. Defendants intended for consumers to rely on their Marketing, and reasonable consumers did in fact so rely. However, Defendants' Marketing is deceptive, misleading, unfair, and/or false because, among other things, the Prenatal Vitamins contained, or had a risk of containing, less Folic Acid than the amount stated on the label.

31. Contrary to the express representations made on their labels, Defendants' Prenatal Vitamins provided or risked providing less Folic Acid than the amount stated on the label.

IV. Defendants' Mismarketing of the Prenatal Vitamins is the Basis for this Action

32. Defendants' wrongful Marketing, which includes misleading, deceptive, unfair, and false Marketing, omissions, and minimizations, allowed them to capitalize on, and reap enormous profits from consumers who paid the price premium for Prenatal Vitamins that were not sold as advertised. Defendants continue to wrongfully induce consumers to purchase the Prenatal Vitamins that are not as advertised.

[acid#:~:text=If%20you%20do%20not%20get%20enough%20folic%20acid%20before%20and,S pina%20bifida](#) (last accessed January 3, 2022) ("Health & Human Services, Folic Acid").

33. Plaintiffs bring this proposed consumer class action individually and on behalf of all other members of the Class (as defined herein), who, from the applicable limitations period up to and including the present, purchased for use and not resale any of Defendants' Prenatal Vitamins.

JURISDICTION AND VENUE

34. This Court has original jurisdiction over all causes of action asserted herein under the Class Action Fairness Act of 2005 ("CAFA"), 28 U.S.C. §1332(d), for the following reasons: (a) some of the class members are citizens of a state that is different from the citizenship of the Defendants; (b) the putative class size is greater than 100 persons; (c) the amount in controversy in the aggregate for the putative class exceeds the sum of \$5 million, exclusive of interest and costs; and (d) the primary defendants do not include States, State officials, and/or other governmental entities against whom the district court may be foreclosed from ordering relief.

35. This Court has original jurisdiction over this action under CAFA, 28 U.S.C. §1332(d), because, upon information and belief, no other class action has been filed asserting the same or similar factual allegations against the defendants on behalf of the same or other persons during the 3-year period preceding the filing of this class action.

General Personal Jurisdiction

36. This Court has personal jurisdiction over Plaintiffs, Mariah Schmucker and Kayla McGowan, who are residents of the State of California.

37. This Court has both general and specific personal jurisdiction over the Defendants, Schwabe North America, Inc. and Nature's Way Brands, LLC.

38. This Court has general personal jurisdiction over Defendant Nature's Way Brands, LLC, because it is registered to conduct business in California.

39. This Court has general personal jurisdiction over Defendants, Schwabe North America, Inc. and Nature's Way Brands, LLC, because the Defendants advertise, market, and sell their parental vitamin products in California, accept money from purchasers located in California, have engaged in systematic and continuous business activities in California, transacted substantial business with California entities and residents, and generally have sufficient minimum contacts in

1 California to satisfy the Due Process Clause of the California Constitution and California's Long
2 Arm Statute pursuant to California Code of Civil Procedure §410.10.

3 **Specific Personal Jurisdiction**

4 40. This Court has specific personal jurisdiction over Defendants arising from
5 Defendants' advertising, Marketing, and sale of Nature's Way prenatal vitamin products in
6 California, which at all relevant times, included or risked including dangerous substances and
7 misrepresented the amount of Folic Acid, all of which have caused harm in California as a result
8 of the specific business activities complained of herein, either directly or through Defendants'
9 agents.

10 41. This Court has specific persona jurisdiction over Defendants because the
11 advertising, Marketing, and sale of Nature's Way prenatal vitamin products, which included or
12 risked including dangerous substances and misrepresented the amount of Folic Acid, occurred in
13 parts of California that are located in the Eastern District of California.

14 42. Venue is proper in the Eastern District of California under 28 U.S.C. §1391(b)(2)
15 because Plaintiffs, Mariah Schmucker and Kayla McGowan, reside in the Eastern District of
16 California, and ingested the Nature's Way prenatal vitamin products at issue within the confines
17 of this District.

18 43. Venue is proper in the Eastern District of California under 28 U.S.C.
19 §1391(b)(1)&(2) and 28 USC §1391(d) because Defendants regularly conduct substantial business
20 within the Eastern District of California.

21 44. Venue is also proper in the Eastern District of California under 28 U.S.C.
22 §1391(b)(2) because a substantial portion of the events or omissions giving rise to Plaintiffs'
23 claims occurred in this District, namely Defendants' advertisement, sale, and Marketing of
24 Nature's Way prenatal vitamin products, which occurred in this District and caused financial harm
25 to members of the putative class that reside in this District.

26 **THE PARTIES**

27 45. Plaintiff Mariah Schmucker is, and at all times relevant hereto has been, a citizen
28 of Pollock Pines, California, located in El Dorado County. She purchased the Prenatal Vitamins

1 for herself from October of 2020 to September of 2021 from the Grocery Outlet in Placerville,
2 California in El Dorado County. She used the Prenatal Vitamins during and after her pregnancy.

3 46. Plaintiff Kayla McGowan is, and at all times relevant hereto has been, a citizen of
4 Hanford, California, located in Kings County. She purchased the Prenatal Vitamins during her
5 pregnancy from December of 2020 until February of 2021. She purchased the Prenatal Vitamins
6 from Walmart in Hanford, California.

7 47. During the time Plaintiffs purchased and took the Prenatal Vitamins, and due to the
8 false and misleading claims and omissions and minimizations by Defendants, Plaintiffs believed
9 they were taking prenatal vitamins to give their bodies the nutrients needed for a healthy
10 pregnancy. Plaintiffs were unaware the Prenatal Vitamins contained, or risked containing,
11 undisclosed levels of Heavy Metals. Plaintiffs also believed the Prenatal Vitamins contained the
12 amount of Folic Acid that was stated on the Product label. Plaintiffs would not have purchased the
13 Prenatal Vitamins if the levels, or risk of levels, of Heavy Metals and amount of Folic Acid had
14 been fully and accurately disclosed and represented.

15 48. As the result of Defendants' negligent, reckless, and/or knowingly deceptive
16 conduct as alleged herein, Plaintiff was injured when she paid the price premium for the Prenatal
17 Vitamins that did not deliver what they promised. Plaintiffs paid the price premium on the
18 assumption that the labeling of the Prenatal Vitamins was accurate, that they did not contain or
19 risk containing undisclosed levels of Heavy Metals and were safe to ingest, and that they contained
20 the amount of Folic Acid promised on the Product label. Plaintiffs would not have paid this money
21 had she known that the Prenatal Vitamins contained, or risked containing, levels of Heavy Metals
22 and contained, or risked containing, a deficient amount of Folic Acid as compared to the amount
23 stated on the Product label. Further, should Plaintiffs encounter the Prenatal Vitamins in the future,
24 they could not rely on the truthfulness of the Marketing, absent corrective changes to the
25 packaging, labeling, and advertising of the Prenatal Vitamins. Damages can be calculated through
26 expert testimony at trial.

27 49. Defendant Schwabe North America, Inc. f/k/a Nature's Way Holding Company
28 ("Schwabe") is organized and existing under the laws of the state of Wisconsin. Schwabe's

1 headquarters and principal place of business are at 825 Challenger Drive, Green Bay, Wisconsin.
2 Defendant Schwabe created, allowed, negligently oversaw, and/or authorized the unlawful,
3 fraudulent, unfair, misleading, and/or deceptive labeling and advertising for the Prenatal Vitamins.

4 50. Defendant Nature's Way Brands, LLC ("Nature's Way") is organized and existing
5 under the laws of the state of Wisconsin. Nature's Way's headquarters and principal place of
6 business is at 825 Challenger Drive, Green Bay, Wisconsin. Nature's Way is wholly-owned by
7 Schwabe North America, Inc. Nature's Way's brands of products include Alive!® and
8 Completia® prenatal vitamins.

9 51. Defendants are responsible for the Marketing, distribution, and sale of the Prenatal
10 Vitamins under the Nature's Way® name to millions of consumers throughout the United States,
11 including this District.

12 52. Plaintiffs are informed and believe, and thus allege, that at all times herein
13 mentioned, each Defendant was the agent, employee, representative, partner, joint venturer, and/or
14 alter ego of the other Defendant and, in doing the things alleged herein, was acting within the
15 course and scope of such agency, employment, representation, on behalf of such partnership or
16 joint venture, and/or as such alter ego, with the authority, permission, consent, and/or ratification
17 of the other Defendant.

18 53. The Marketing for the Prenatal Vitamins, relied upon by Plaintiffs, was
19 disseminated throughout the United States, including this District, by Defendants and their agents
20 through advertising, packaging, and labeling that contained the misrepresentations and omissions
21 alleged herein. Defendants' Marketing for the Prenatal Vitamins was designed to encourage
22 consumers, and reasonably misled consumers, into purchasing the Prenatal Vitamins throughout
23 the United States, including this District.

24 54. Defendants manufacture, market, advertise, package, and label several prenatal
25 vitamin products. Defendants' Prenatal Vitamins include, but are not limited to:²⁰

26

27 _____

28 ²⁰ As stated *supra*, discovery may reveal additional products that contain Heavy Metals and reflect
an amount of Folic Acid than is stated on the product label. Plaintiffs reserves their right to include

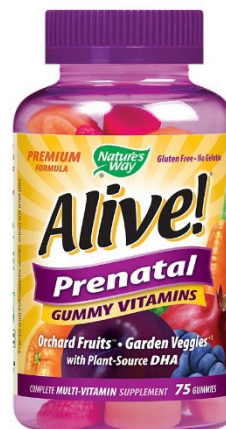
(a) Nature's Way Alive!® Complete Prenatal Multi-Vitamin:



(b) Nature's Way Prenatal Multi-Vitamin and Multi-Mineral:



(c) Nature's Way Alive!® Prenatal Gummy:



any such products in this action. Plaintiffs reserve their right to amend and/or supplement the labels included in the Complaint in accordance with applicable Federal and California law.

(d) Nature's Way Completia® Prenatal Multi-Vitamin:



FACTUAL ALLEGATIONS

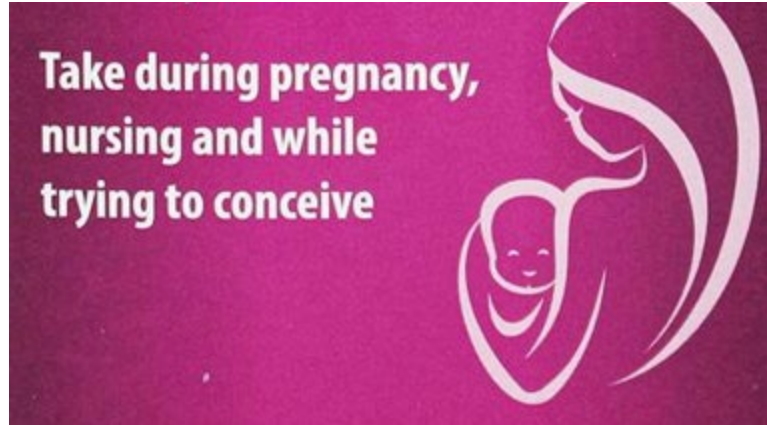
I. DEFENDANTS' MARKETING PRACTICES EMPHASIZED THEIR PRENATAL VITAMINS AS THE HIGHEST STANDARD

55. Defendants' package, label, market, advertise, formulate, manufacture, distribute, and sell their products, including their Prenatal Vitamins, throughout this District and the United States, and their Products are widely advertised and available at numerous retail and online outlets. Defendants' Marketing promotes their Products as the highest standard for consumers.

56. Defendants' Prenatal Vitamins are advertised with the "Nature's Way®" brand to reflect and imply that the Products are natural. "Nature's Way®" is placed on a green leaf on all of Defendants' Nature's Way® Products, including the Prenatal Vitamins.



1 57. Defendants' Prenatal Vitamin packaging includes images of a woman nurturing a
2 baby with the directions to "take during pregnancy, nursing and while trying to conceive."



11
12
13 58. On their website, Defendants' promise "A Legacy of Quality" and encourage
14 consumers to "Trust the Leaf™."²¹

15
16
17

A dark gray rectangular box containing the text "A Legacy of Quality Trust the Leaf™" in green and white.

28 ²¹ <https://www.naturesway.com/quality> (last accessed January 3, 2022).

1 59. Defendants also declare on their website that, “When it comes to quality, we don’t
2 follow the crowd...we lead the industry,” and that they are “Setting the Gold Standard for
3 Quality.”²²

4
5 When it comes to quality, we don’t follow the crowd...we lead
6 the industry.

7
8
9 Setting the Gold Standard for Quality

10 At Nature’s Way, quality is more than a set of tests. It’s about doing the right thing – every
11 time – without compromise.
12

13
14 60. With their marketed natural Products, trusted leadership, and “legacy,” Defendants
15 clearly recognize the importance of the Prenatal Vitamins to the healthy development of a baby
16 in-utero, including a woman’s preparation to foster such development.

17 **II. DEFENDANTS’ SOURCING, MANUFACTURING, AND TESTING**
18 **PROCEDURES PROVIDED THEM WITH EXCLUSIVE KNOWLEDGE OF THE**
19 **PHYSICAL AND CHEMICAL MAKE-UP OF THE PRENATAL VITAMINS**

20 61. Defendants have, and had, exclusive knowledge of the physical and chemical make-
21 up of the Prenatal Vitamins.

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28 ²² *Id.*

62. Defendants’ website describes their established and personal role in sourcing and ingredients.²³ Defendants have “partnered with farmers, gatherers, and suppliers, with many generations of experience, when creating our products.”²⁴



SOURCING & INGREDIENTS

QUALITY STARTS AT THE SOURCE

We travel the globe to bring you the best ingredients possible. For over 50 years, we’ve partnered with farmers, gatherers, and suppliers, many with generations of experience, when creating our products. Our ingredients are grown and harvested with respect for the planet, many without bioengineered ingredients (GMOs).

63. On their website, Defendants promote their “manufacturing excellence, stating they have “exceeded industry standards” and “set the bar for the industry.”²⁵ They also state that they were the “first recognized Good Manufacturing Practices (GMP) by the NSF [National Sanitation Foundation].”²⁶



MANUFACTURING

MANUFACTURING EXCELLENCE

We’ve exceeded industry standards for decades. We were the first recognized Good Manufacturing Practices (GMP) facility by NSF and continue to set the bar for the industry today.

We are leaders of groups including the Council of Responsible Nutrition and the Natural Products Association, organizations that continue to elevate dietary supplement standards to ensure better products for all.

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*

1
2 64. Defendants’ website describes their product testing, stating their Products are
3 “Consciously Crafted. Expert Verified.”²⁷ Defendants “go above and beyond to ensure what’s on
4 the label is what’s in your bottle” and advertise that their “team of professionals performs thorough
5 testing on every ingredient in our onsite state-of-the-art lab – an investment that’s a rarity in the
6 industry.”²⁸

7 65. With their marketed testing and manufacturing procedures, and robust partnerships,
8 Defendants clearly recognize the importance of quality ingredients in their Prenatal Vitamins, as
9 well as accurate representation of the amount of those ingredients on the Product label, to the
10 healthy development of a baby in-utero, including a woman’s preparation to foster such
11 development.

12 **III. DEFENDANTS FAIL TO DISCLOSE THE PRESENCE OR RISK OF HEAVY**
13 **METALS IN THE PRENATAL VITAMINS**

14 **A. Defendants Falsely Marketed the Prenatal Vitamins by Omitting the Inclusion, or**
15 **Risk of Heavy Metals**

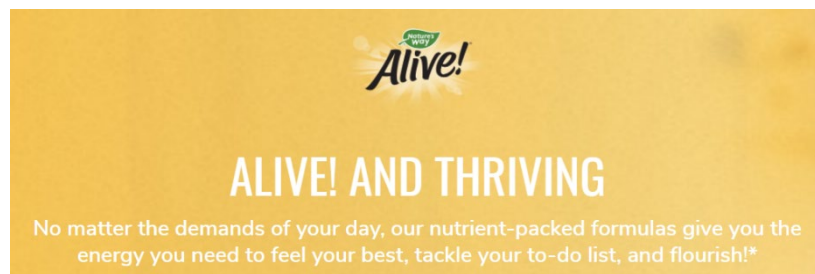
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27 ²⁷ *Id.*

28 ²⁸ *Id.*

66. Defendants promote their Prenatal Vitamins as Products made with “premium quality” or with a “complete formula” or “premium formula.”



67. Defendants explain on their website that their brand Alive!® is “Alive! And Thriving” with “nutrient-packed formulas.”²⁹



²⁹ <https://www.naturesway.com/brands/alive> (last accessed January 3, 2022).

68. Defendants label their Products as “Formulated for Pregnant and Nursing Women” and “Advanced Prenatal for Mom & Developing Baby.”



69. Based on Defendants’ decision to advertise, label, and market the Prenatal Vitamins as natural, nutritious, and nurturing of a healthy pregnancy, consistent with the Nature’s Way brand, they had a duty to ensure that these statements were true and not misleading. As such, Defendants knew or should have known that the Prenatal Vitamins included, or risked including, nondisclosed levels of Heavy Metals, especially considering Defendants’ statements on its website, labels, and packaging.

70. Defendants’ Marketing of the Products failed to disclose they contained or were at risk of containing any level of Heavy Metals. In the case of one Product, Alive!® Complete Prenatal Multi-Vitamin, a “Smarter Prenatal,” Defendants’ Marketing blatantly minimized the presence of undisclosed level of Mercury. For instance, Defendants’ only state that the Product Alive!® Complete Prenatal Multi-Vitamin “does not contain harmful mercury levels,” without disclosing that the Product contains or risks containing levels of mercury that are above, or risk

being above, the levels recommended for drinking water, and without warning consumers about the adverse health effects of exposure to Mercury, especially to an in-utero child.



71. Defendants intentionally omitted or minimized the inclusion of Heavy Metals in their Products in order to induce and mislead reasonable consumers to purchase their Prenatal Vitamins.

72. As a result of Defendants' omissions and minimizations, a reasonable consumer would have no reason to suspect the presence, or risk, of undisclosed levels of Heavy Metals in the Products without conducting his or her own scientific tests or reviewing third party scientific testing of these Products.

B. Due to the Presence of Heavy Metals in the Prenatal Vitamins, Defendants' Marketing and Omissions are Misleading

73. At all times during the Class Period, Defendants knew or should have known the Prenatal Vitamins contained, or risked containing, Heavy Metals.

74. Defendants thoroughly test every ingredient on-site, which is a "rarity" in the industry.³⁰ In fact, Defendants knew that one Product contained Mercury, but failed to disclose the level of contamination in the Product. Additionally, as a result of a publicly released 2008 Food and Drug Administration ("FDA") survey of vitamins which included prenatal vitamins ("2008

³⁰ <https://www.naturesway.com/quality> (last accessed January 3, 2022).

1 FDA Survey”), Defendants knew or should have known several of their children’s and women’s
2 vitamins, including a prenatal vitamin,³¹ were contaminated with Lead.

3 75. Plaintiffs, through counsel, submitted a Freedom of Information Act (“FOIA”)
4 request to the FDA on March 9, 2021, asking for any tests results or any records related to the
5 levels of Folic Acid or Heavy Metals in Nature’s Way prenatal vitamins. As of the date of this
6 filing, Plaintiffs have not received a response from the FDA.

7 76. Defendants’ Prenatal Vitamins contained or had a risk of containing Heavy Metals.
8 Defendants were aware of this risk due to their proclaimed sourcing, manufacturing, and testing
9 procedures, and Defendants failed to disclose it to Plaintiffs and the Class. Defendants only chose
10 to acknowledge the presence of Mercury in one Product, the Alive!® Complete Prenatal Multi-
11 Vitamin, stating that the Product “does not contain harmful mercury levels.” But Defendants failed
12 to disclose the actual and potentially harmful, levels of Mercury in that Product. For instance, the
13 Alive!® Complete Prenatal Multi-Vitamin contains or risks containing levels of Mercury that are
14 above, or risk being above, the levels recommended for drinking water.. Defendants also failed to
15 warn consumers of the risks associated with consuming any level of Mercury and exposing a
16 developing child to Mercury while pregnant, or prior to becoming pregnant.

17 77. Defendants knew or should have known that Heavy Metals are potentially
18 dangerous contaminants that pose health risks to humans, especially to women who are pregnant
19 or may become pregnant and developing babies.

20 78. Heavy Metal exposure can lead to catastrophic health consequences in a developing
21 baby. The fetal development period from conception until birth is a phase of life that carries
22 particular vulnerability to toxic exposure, including Heavy Metals, as developing babies have an
23 immature detoxification capability.³² Due to this vulnerable state, during this critical period, a

24 _____
25 ³¹ FDA, “Survey Data on Lead in Women’s and Children’s Vitamins,” August 2008, *available at*
26 [https://www.fda.gov/food/metals-and-your-food/survey-data-lead-womens-and-childrens-](https://www.fda.gov/food/metals-and-your-food/survey-data-lead-womens-and-childrens-vitamins#ftn2)
[vitamins#ftn2](https://www.fda.gov/food/metals-and-your-food/survey-data-lead-womens-and-childrens-vitamins#ftn2) (last accessed January 3, 2022) (“2008 FDA Survey”).

27 ³²Heavy metal contamination of prenatal vitamins, *available at*
28 <https://www.sciencedirect.com/science/article/pii/S2214750018301215?via%3Dihub> (last
accessed January 3, 2022) (“Heavy Metal Contamination of Prenatal Vitamins”).

1 child may amass higher levels of Heavy Metals and thus experience higher levels of toxic exposure
2 than their mothers.³³ This exposure may lead to adverse consequences in pregnancy and to the in-
3 utero baby, including premature delivery, and the baby having a decreased birth weight, as well as
4 smaller head and chest circumference, and a multitude of developmental and long-term health
5 problems.³⁴ Prenatal exposure to Heavy Metals also negatively affects a child's neurodevelopment
6 and may contribute to schizophrenia and dementia in adulthood.³⁵

7 79. Defendants knew or should have known they owed consumers a duty of care to
8 prevent the presence or risk of Heavy Metals in the Prenatal Vitamins to the extent reasonably
9 possible.

10 80. Defendants knew or should have known they owed consumers a duty of care to
11 disclose the presence, or risk, of Heavy Metals in the Prenatal Vitamins.

12 81. Defendants knew or should have known consumers purchased their Prenatal
13 Vitamins based on the reasonable expectation that Defendants manufactured the Products to the
14 highest standards. Based on this expectation, Defendants knew or should have known consumers
15 reasonably inferred that Defendants would hold the Prenatal Vitamins to the highest standards for
16 preventing the inclusion of Heavy Metals in their Products and for the testing for Heavy Metals in
17 the Prenatal Vitamins' ingredients as well as the final Products.

18 **Heavy Metal Ingredient: Arsenic**

19 82. Defendants' Prenatal Vitamins contain, or risk containing, Arsenic, which can
20 cause cancer in humans, as well as diabetes and atherosclerosis, and potentially cardiovascular
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26 ³³ *Id.*

27 ³⁴ *Id.*

28 ³⁵ *Id.*

disease when ingested chronically.³⁶ Chronic exposure to Arsenic has also been associated with dermatological lesions and malignancies.³⁷

83. For children specifically, the World Health Organization (“WHO”) has found that prenatal exposure to Arsenic through placental transfer, “can cause marked damage to the fetus[]” and increases the risk of detrimental effects throughout early childhood.³⁸ Exposure to Arsenic in-utero “has recently been associated with impact on genetic homeostasis with resulting inflammation and atherosclerotic disease adults.”³⁹ Inorganic Arsenic exposure in-utero is also linked to “impaired intellectual development, such as decreased performance on certain developmental tests that measure learning.”⁴⁰ A developing baby’s exposure to Arsenic also contributes to cardiovascular disease later in life.⁴¹

84. Exposure cannot be undone, as “[t]here is no evidence that the harm caused by arsenic is reversible.”⁴² Moreover, Arsenic exposure may increase the mother’s risk of nausea and

³⁶ States JC, Singh AV, Knudsen TB, Rouchka EC, Ngalame NO, Arteel GE, et al. (2012) Prenatal Arsenic Exposure Alters Gene Expression in the Adult Liver to a Proinflammatory State Contributing to Accelerated Atherosclerosis. PLoS ONE 7(6): e38713. Available at <https://doi.org/10.1371/journal.pone.0038713> (last accessed January 3, 2022) (“Prenatal Arsenic Exposure”).

³⁷ Genuis SJ, Schwalfenberg G, Siy A-KJ, Rodushkin I (2012) Toxic Element Contamination of Natural Health Products and Pharmaceutical Preparations. PLOS ONE 7(11): e49676. Available at <https://doi.org/10.1371/journal.pone.0049676> (last accessed January 3, 2022) (“Toxic Element Contamination of Natural Health Products”).

³⁸ WHO, Adverse Health Effects of Heavy Metals in Children, available at https://www.who.int/ceh/capacity/heavy_metals.pdf (last accessed January 3, 2022).

³⁹ *Heavy metal contamination of prenatal vitamins, supra.*

⁴⁰ U.S. Food and Drug Administration, “Arsenic in Food and Dietary Supplements,” current as of August 5, 2020, available at <https://www.fda.gov/food/metals-and-your-food/arsenic-food-and-dietary-supplements> (last accessed January 3, 2022) (“Arsenic in Supplements”).

⁴¹ *Prenatal Arsenic Exposure, supra.*

⁴² Healthy Babies Bright Futures Report, What’s in My Baby’s Food, at 3, available at https://www.healthybabyfood.org/sites/healthybabyfoods.org/files/2020-04/BabyFoodReport_ENGLISH_R6.pdf (last accessed January 3, 2022) (“Healthy Babies Bright Futures Report”).

vomiting during pregnancy, which may decrease maternal weight gain and lead to poor maternal nutrition.⁴³ A woman’s blood Arsenic was also associated with decreased fetal growth.⁴⁴

85. Based on the risks associated with exposure to higher level of Arsenic, both the U.S. Environmental Protection Agency (“EPA”) and FDA have set limits concerning the allowable limit of Arsenic at 10 parts per billion (“ppb”) for human consumption in apple juice (regulated by the FDA) and drinking water (regulated by the EPA as a maximum contaminant level).⁴⁵ The FDA has also set the maximum allowable levels in bottled water at 10 ppb of inorganic Arsenic.⁴⁶

86. Although the FDA has not set the action level for Arsenic in prenatal supplements specifically, “the FDA prioritizes monitoring and regulating products that are more likely to be consumed by very young children.”⁴⁷ In that vein, the FDA issued guidance limiting the action level for Arsenic in infant rice cereals to 100 ppb.⁴⁸

87. Notwithstanding the establishment of action levels, Arsenic exposure may result in adverse outcomes during pregnancy and in the developing child.⁴⁹

⁴³ Estimating Effects of Arsenic Exposure During Pregnancy on Perinatal Outcomes in a Bangladeshi Cohort, *Epidemiology*, 2016 Mar; 27(2); 173-181, published online 2016 Feb 2, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4733817/> (last accessed January 3, 2022) (“Estimating Effects of Arsenic Exposure During Pregnancy”).

⁴⁴ Claus Henn, B., Ettinger, A. S., Hopkins, M. R., Jim, R., Amarasiriwardena, C., Christiani, D. C., Coull, B. A., Bellinger, D. C., & Wright, R. O. (2016). Prenatal Arsenic Exposure and Birth Outcomes among a Population Residing near a Mining-Related Superfund Site. *Environmental health perspectives*, 124(8), 1308–1315. Available at <https://doi.org/10.1289/ehp.1510070> (last accessed January 3, 2022) (“Prenatal Exposure and Birth Outcomes”).

⁴⁵ *Arsenic in Supplements, supra*.

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ *Heavy metal contamination of prenatal vitamins, supra*.

1 **Heavy Metal Ingredient: Cadmium**

2 88. Defendants' Prenatal Vitamins contain, or risk containing, Cadmium, which is
3 linked to neurotoxicity, cancer, and kidney, bone, and heart damage.⁵⁰ Moreover, the U.S.
4 Department of Health and Human Services ("HHS") has determined that Cadmium is a probable
5 human carcinogen.⁵¹

6 89. Cadmium exposure during pregnancy can lead to detrimental outcomes. "Maternal
7 exposure to [cadmium] has been associated with the delivery of low-birth weight babies and an
8 increase incidence of spontaneous abortion."⁵² Cadmium may displace zinc, which is essential for
9 normal fetal growth and development as well as maternal health during pregnancy.⁵³

10 90. Cadmium may seriously affect the morbidity and mortality of newborns in the first
11 four weeks of their lives with far-reaching health consequences.⁵⁴ Scientists have reported a
12 "tripling of risk for learning disabilities and special education among children with higher
13 cadmium exposures, at levels common among U.S. children[.]"⁵⁵ Cadmium is also associated with
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18 ⁵⁰ Genchi, G., Sinicropi, M.S., Lauria, G., Carocci, A., & Catalano, A., "The Effects of Cadmium
19 Toxicity," International Journal of Environmental Research and Public Health, Review, Published
20 May 26, 2020, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7312803/#:~:text=Cadmium%20accumulates%20in%20plants%20and,%2C%20pancreas%2C%20and%20kidney%20cancers> (last accessed January 3, 2022).

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22 ⁵¹ Agency for Toxic Substances and Disease Registry, Public Health Statement, "Cadmium,"
23 (Sept. 2012), available at <https://www.atsdr.cdc.gov/phs/phs.asp?id=46&tid=15> (last accessed
January 3, 2022).

24 ⁵² *Id.*

25 ⁵³ *Id.*

26 ⁵⁴ Ikeh-Tawari, E. P., Anetor, J. I., & Charles-Davies, M. A. (2013). Cadmium level in pregnancy,
influence on neonatal birth weight and possible amelioration by some essential trace
27 elements. *Toxicology international*, 20(1), 108–112. Available at <https://doi.org/10.4103/0971-6580.111558> (last accessed January 3, 2022).

28 ⁵⁵ *Healthy Babies Bright Futures Report at 14, supra.*

decreases in IQ⁵⁶ and the development of ADHD.⁵⁷ Compounding the concern is that Cadmium has a prolonged half-life as it sequesters in body tissue.⁵⁸

91. Although the FDA has not set the maximum contaminant level for Cadmium in prenatal vitamins, the EPA has set a maximum contaminant level for Cadmium in drinking water of 5 ppb, 40 C.F.R. §141.62; the FDA has set a maximum level in bottled water to 5 ppb, and the WHO set a maximum cadmium level in drinking water to 3 ppb.⁵⁹ Regardless, Cadmium, like Lead, “displays a troubling ability to cause harm at low levels of exposure.”⁶⁰

Heavy Metal Ingredient: Lead

92. Defendants’ Prenatal Vitamins contain, or risk containing, Lead, which is a probable carcinogen⁶¹ and developmental toxin known to cause health problems to children in-utero.⁶² The Centers for Disease Control and Prevention (“CDC”) reported that exposure to Lead in-utero can negatively affect the development of a baby’s nervous system, decrease a baby’s growth, and increase the risk for a baby being born premature and miscarriage.⁶³

⁵⁶ “Cadmium exposure and cognitive abilities and behavior at 10 years of age: A prospective cohort study,” *Environment International*, Vol. 113, April 2018, Pps. 259-268 *available at* <https://www.sciencedirect.com/science/article/pii/S0160412017321025> (last accessed January 3, 2022).

⁵⁷ Lee, M. J., Chou, M. C., Chou, W. J., Huang, C. W., Kuo, H. C., Lee, S. Y., & Wang, L. J. (2018). Heavy Metals' Effect on Susceptibility to Attention-Deficit/Hyperactivity Disorder: Implication of Lead, Cadmium, and Antimony. *International journal of environmental research and public health*, 15(6), 1221. *Available at* <https://doi.org/10.3390/ijerph15061221> (last accessed January 3, 2022).

⁵⁸ *Toxic Element Contamination of Natural Health Products*, *supra*.

⁵⁹ *Congressional Committee Report*, *supra*, at 29.

⁶⁰ *Healthy Babies Bright Futures Report* at 14, *supra*.

⁶¹ American Cancer Society, “Known and Probable Carcinogens,” Last Revised August 14, 2019, *available at* <https://www.cancer.org/cancer/cancer-causes/general-info/known-and-probable-human-carcinogens.html> (last accessed January 3, 2022).

⁶² *Heavy metal contamination of prenatal vitamins*, *supra*.

⁶³ CDC, Guidelines for the Identification and Management of Lead Exposure in Pregnant and Lactating Women, *available at* <https://www.cdc.gov/nceh/lead/publications/leadandpregnancy2010.pdf> (last accessed January 3, 2022) (“Lead Exposure in Pregnant and Lactating Women”).

1 93. Prenatal Lead exposure can seriously harm a baby’s neurodevelopment, and is
2 associated with a range of negative health outcomes such as schizophrenia and dementia,
3 decreased cognitive performance, and reduced postnatal growth.⁶⁴ Prenatal exposures to the
4 highest and lowest levels of Lead were linked to a heightened risk of autism spectrum diagnosis
5 in children.⁶⁵ Additionally, studies have established a link between Lead exposure and ADHD.⁶⁶

6 94. Prenatal Lead exposure is also linked to an increased risk of a preterm birth and
7 reduced postnatal development.⁶⁷ Maternal Lead exposure may also contribute to the baby
8 developing certain types of congenital heart disease.⁶⁸

9 95. Due to the danger of Lead exposure, maximum Lead levels are required for certain
10 consumer products:

11 (a) On January 15, 2021, the EPA issued Lead and Copper Rule Revisions, with
12 a new “trigger level” for treatment of 10 ppb lead in drinking water, effective March 16, 2021. 86
13 F.R. 28691 (Jan. 15, 2021). The previous level had been 15 ppb. 40 C.F.R. §141, Subpart I.

14 (b) The FDA requires that bottled water cannot contain more than 5 ppb of total
15 Lead. 21 C.F.R. §165.110(b)(4)(iii)(A).

16 (c) The European Union has set the maximum Lead level in infant formula to
17 20 ppb.

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⁶⁴ *Heavy metal contamination of prenatal vitamins, supra.*

24 ⁶⁵ “ADHD and Autism Associated with In-Utero Heavy Metals and Essential Minerals,”
25 Neuroscience News, April 9, 2021, available at <https://neurosciencenews.com/asd-adhd-heavy-metals-18207/> (last accessed January 3, 2022).

26 ⁶⁶ *Congressional Committee Report, supra.*

27 ⁶⁷ *Heavy metal contamination of prenatal vitamins, supra.*

28 ⁶⁸ *Id.*

Although no federal standard for Lead in prenatal vitamins has been established,⁶⁹ there is no known “safe” level of Lead exposure.⁷⁰ Prenatal children are at risk of developing behavior and cognitive function impairments due to exposure to Lead at levels far lower than those identified as “safe.”⁷¹

Heavy Metal Ingredient: Mercury

96. Defendants’ Prenatal Vitamins contain, or risk containing, Mercury, which increases the risk for cardiovascular disease and can cause vision, intelligence, and memory problems for children exposed in-utero.⁷²

97. Developing fetuses are exceptionally vulnerable to Mercury exposure.⁷³ In a pregnant woman, Mercury can easily pass through the placenta and accumulate in the fetus as the fetus cannot excrete Mercury.⁷⁴ This lack of self-defense leaves a baby in-utero exposed to Mercury that may result in decreased placental and fetal development,⁷⁵ and permanent damage to the nervous system.⁷⁶

⁶⁹ 2008 FDA Survey, *supra* (although no federal standard for Lead exposure has been established, the FDA determined a provisional total tolerable intake level (PTTI) of 25 µg of lead per day for pregnant or lactating women). California’s Proposition 65 and U.S. Pharmacopeia limits are 0.5 µgm/day.

⁷⁰ *Heavy metal contamination of prenatal vitamins, supra.*

⁷¹ *Id.*

⁷² Current Problems in Pediatric Adolescent Health Care, “Mercury Exposure and Children’s Health,” 2010 Sept., available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3096006/> (last accessed January 3, 2022) (“Mercury Exposure and Children’s Health”).

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ Prenatal mercury exposure and birth outcomes, available at <https://www.sciencedirect.com/science/article/abs/pii/S0013935116302857> (last accessed January 3, 2022) (“Prenatal Mercury Exposure and Birth Outcomes”).

⁷⁶ *Mercury Exposure and Children’s Health, supra.*

1 98. Although there is no maximum contaminant level for Mercury in prenatal vitamins,
2 the EPA has set a maximum contaminant level for Mercury in drinking water at 2 ppb.⁷⁷ However,
3 “there is no known safe level” of exposure to Mercury as it is a “highly toxic element.”⁷⁸

4 99. Exposure to any of the four Heavy Metals – Arsenic, Cadmium, Lead, and Mercury
5 – pose significant detriments to children, especially during the gestational period.⁷⁹ Of additional
6 concern to developing babies are the health risks due to exposure to multiple Heavy Metals
7 simultaneously, as “co-exposures can have interactive adverse effects.”⁸⁰

8 100. Understanding the detriment that exposure to Heavy Metals can create, the FDA
9 has acknowledged that “exposure to [these four heavy] metals are likely to have the most
10 significant impact on public health” and has prioritized them in connection with its Toxic Elements
11 Working Group, which is aimed toward reducing human exposure to contaminants in dietary
12 supplements, food and cosmetics.⁸¹

13 101. Despite the known risks of exposure to these Heavy Metals, Defendants have
14 negligently, recklessly, and/or knowingly sold the Prenatal Vitamins without disclosing they
15 contain or may contain undisclosed levels of Arsenic, Cadmium, Lead, and Mercury to consumers
16 like Plaintiffs.

17 102. Based on the foregoing, reasonable consumers, like Plaintiffs, would consider the
18 inclusion, or risk of inclusion, of Heavy Metals a material fact when considering what prenatal
19 vitamin to purchase.

20 ⁷⁷ *Congressional Committee Report, supra.*

21 ⁷⁸ *Mercury Exposure and Children’s Health, supra.*

22 ⁷⁹ *Heavy metal contamination of prenatal vitamins, supra.*

23 ⁸⁰ Morello-Frosch R, Cushing LJ, Jesdale BM, Schwartz JM, Guo W, Guo T, Wang M, Harwani
24 S, Petropoulou SE, Duong W, Park JS, Petreas M, Gajek R, Alvaran J, She J, Dobraca D, Das R,
25 Woodruff TJ. Environmental Chemicals in an Urban Population of Pregnant Women and Their
26 Newborns from San Francisco. *Environ Sci Technol.* 2016 Nov 15;50(22):12464-12472. doi:
10.1021/acs.est.6b03492. Epub 2016 Oct 26. PMID: 27700069; PMCID: PMC6681912. Available
at <https://stacks.cdc.gov/view/cdc/80511> (last accessed January 3, 2022).

27 ⁸¹FDA, “Metals and Your Food,” Current as of April 8, 2021, available at
28 <https://www.fda.gov/food/chemicals-metals-pesticides-food/metals-and-your-food> (last accessed
January 3, 2022).

1 103. Defendants knew that monitoring for Heavy Metals in their ingredients and Prenatal
2 Vitamins was not only important but critical.

3 104. Defendants also knew that monitoring Heavy Metals was likewise important to
4 their health-conscious consumers.

5 105. Finally, Defendants knew or should have known they could control the levels of
6 Heavy Metals in the Prenatal Vitamins by adequately monitoring their ingredients for Heavy
7 Metals and adjusting any formulation to reduce ingredients that contained higher levels of Heavy
8 Metals. Moreover, the 2008 FDA Survey put Defendants on notice that some of the Prenatal
9 Vitamins contained Lead.

10 106. Defendants also knew they were not monitoring and testing for Heavy Metals in
11 the Prenatal Vitamins. Defendants knew their failure to test for Heavy Metals in the Prenatal
12 Vitamins continued throughout the Class Period.

13 107. Defendants' Marketing was misleading due to their failure to properly and
14 sufficiently monitor for Heavy Metals and for failure to disclose the risk or presence of Heavy
15 Metals in the Prenatal Vitamins.

16 108. Defendants knew or should have known consumers paid the price premium and
17 expected Defendants to test and monitor for Heavy Metals and disclose the risk or presence of
18 Heavy Metals in the Prenatal Vitamins and ingredients.

19 109. At all times during the Class Period, Defendants did not monitor or test for Heavy
20 Metals in the Prenatal Vitamins and ingredients and Defendants did not disclose the presence or
21 risk of Heavy Metals in their Products.

22 110. Defendants only chose to disclose that one Product contained non-harmful levels
23 of Mercury without disclosing the actual levels the Product contained and without warning
24 consumers of the adverse health consequences of consuming Mercury while pregnant.

25 111. Defendants knew or should have known that consumers reasonably expected them
26 to test for and monitor the presence of Heavy Metals in the Prenatal Vitamins and ingredients, and
27 to disclose the presence or risk of any levels of Heavy Metals in their Products.

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112. Defendants knew or should have known the Prenatal Vitamins contained or risked containing Heavy Metals that were inconsistent with their Marketing.

113. Defendants knew or should have known that, in order to comply with their Marketing, consumers expected them to ensure the Prenatal Vitamins were monitored and tested for Heavy Metals, and to disclose the presence or risk of Heavy Metals.

114. Defendants knew, yet failed to disclose, their lack of testing and knowledge of the risk or presence of Heavy Metals in the Prenatal Vitamins ingredients.

115. Defendants' above-referenced statements, representations, partial disclosures, and omissions are false, misleading, and crafted to deceive the public as they create an image that the Prenatal Vitamins are nutritious and free of Heavy Metals.

116. Moreover, reasonable consumers, such as Plaintiffs and the Class members, would have no reason to doubt Defendants' statements regarding the quality of the Prenatal Vitamins. Defendants' nondisclosure, partial disclosure, and/or concealment of the presence or risk of Heavy Metals in the Prenatal Vitamins, coupled with the misrepresentations alleged herein, were intended to and did, in fact, cause consumers like Plaintiffs and the members of the Class to purchase the Products they would not have if the true quality and ingredients were disclosed.

C. Defendants' Marketing Misled and Deceived Consumers to Believe that the Prenatal Vitamins Do Not Contain or Risk Containing Heavy Metals

117. Defendants' Marketing wrongfully represents to consumers that the Prenatal Vitamins have certain superior quality and characteristics that they do not actually possess.

118. Although Defendants misleadingly caused consumers to believe their Prenatal Vitamins do not contain or risk containing Heavy Metals through their Marketing, omissions, and minimizations, the Products do in fact contain or risk containing undisclosed Heavy Metals, which is material information to reasonable consumers.

119. Plaintiffs' counsel had Defendants' Prenatal Vitamins tested and that testing confirmed that each of Defendants' Prenatal Vitamins that were tested contained or risked containing undisclosed Heavy Metals.

1 120. The highest levels of Arsenic were 1164.63 ppb in Nature's Way Completia®
2 Prenatal Multi-Vitamin (240 count), and 1109.90 ppb in Nature's Way Prenatal Multi-Vitamin.

3 121. The highest levels of Cadmium were 211.60 ppb in Nature's Way Prenatal Multi-
4 Vitamin, and 130.32 ppb in Nature's Way Alive!® Complete Prenatal Multi-Vitamin.

5 122. The highest levels of Lead were 127.10 ppb in Nature's Way Prenatal Multi-
6 Vitamin.

7 123. The highest levels of Mercury were 34.27 ppb in Nature's Way Completia®
8 Prenatal Multi-Vitamin (240 count). "Even the Product that discloses it 'does not contain harmful
9 mercury levels' contained levels of 3.43 and 4.40 ppb of mercury, which are levels over the 2 ppb
10 allowable for drinking water.

11 124. However, as stated herein, no level of Heavy Metals is safe.

12 125. Defendants' Marketing wrongfully fails to disclose to consumers the presence or
13 risk of Heavy Metals in their Prenatal Vitamins. Additionally, in the case of one Product, while
14 acknowledging it contains Mercury, Defendants minimize its presence (stating on the Product label
15 that it "does not contain harmful mercury levels") and fail to disclose the level of Mercury in the
16 Product.

17 126. Based on Defendants' Marketing, a reasonable consumer would not suspect the
18 presence or risk of Heavy Metals, or any harmful level of a Heavy Metal, nor would a reasonable
19 consumer be able to detect the presence of Heavy Metals in the Prenatal Vitamins without
20 conducting his or her own scientific tests or reviewing scientific testing of the Products.

21 127. Reasonable consumers must and do rely on Defendants to honestly report what the
22 Prenatal Vitamins contain.

23 128. In light of Defendants' Marketing, Defendants knew or should have known the
24 Prenatal Vitamins contained or risked containing Heavy Metals.

25 129. Defendants intended for consumers to rely on their Marketing, and reasonable
26 consumers did in fact so rely.

27 130. Defendants had a duty to ensure the Prenatal Vitamins were as they were
28 represented and not deceptively, misleadingly, unfairly, and falsely marketed.

131. Pursuant to the foregoing, Defendants' Marketing is deceptive, misleading, unfair, and false to Plaintiffs and other consumers, including under the consumer protection laws of California, as described more fully herein.

132. Defendants acted negligently, recklessly, unfairly, and/or intentionally with their deceptive, misleading, unfair, and false Marketing, omissions, and minimizations.

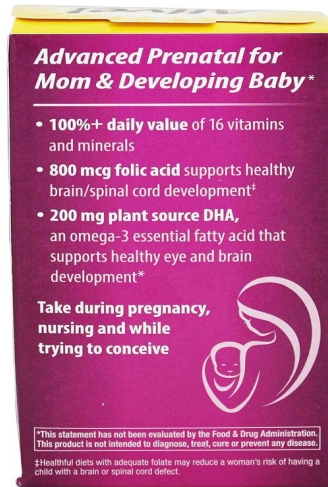
IV. DEFENDANTS MISREPRESENT THE AMOUNT OF FOLIC ACID IN THE PRENATAL VITAMINS

A. Defendants Falsely Market the Amount of Folic Acid in their Prenatal Vitamins

133. Defendants market the Prenatal Vitamins as containing "High Potency Folic Acid," made with "100% Daily Value 16 Vitamins & Minerals," and "Formulated for Pregnant and Nursing Women with [...] Folic Acid."



134. Defendants' Products are marketed as "Premium Quality" and "Advanced Prenatal for Mom & Developing Baby" with "800 mcg [micrograms] folic acid" that "supports healthy brain/spinal cord development."



135. Each of Defendants' Products states on the "Supplement Facts" label that it provides a certain amount of Folic Acid per serving.⁸²

⁸² In accordance with the Federal Rule for New Supplement Facts Labeling, companies like Defendants now state on their label a "[Percentage] Daily Value for the total amount of Folate in a product, and if any of the total Folate comes from Folic Acid, that amount of Folic Acid is listed in mcg in parentheses." See U.S. Food and Drug Administration, "Folate and Folic Acid on the Nutrition and Supplement Facts Labels," June 29, 2020, available at <https://www.fda.gov/food/new-nutrition-facts-label/folate-and-folic-acid-nutrition-and-supplement-facts-labels> (last accessed January 3, 2022).

(a) Nature's Way Alive!® Complete Prenatal Multi-Vitamin:

Nature's Way - Alive! Complete Prenatal Multivitamin Berry - 60 Vegetarian Softgels

Supplement Facts

Serving Size: 2 Softgels

Servings Per Container: 30

	Amount Per Serving	% Daily Value
Calories	15	
Calories from Fat	10	
Total Fat	1.5 g	2%*
Total Carbohydrate	< 1 g	1%*
Vitamin A (50% as retinyl palmitate, 50% as beta carotene)	8000 IU	100%
Vitamin C (as calcium ascorbate)	60 mg	100%
Vitamin D3 (as cholecalciferol)	600 IU	150%
Vitamin E (as dl-alpha tocopherol)	30 IU	100%
Vitamin B1 (as thiamin mononitrate)	3.4 mg	200%
Vitamin B2 (riboflavin)	40 mg	200%
Vitamin B3 (as niacinamide)	2 mg	100%
Vitamin B6 (as pyridoxine HCl)	5 mg	200%
Folic Acid	800 mcg	100%
Vitamin B12 (as methylcobalamin)	16 mcg	200%
Biotin	300 mcg	100%
Vitamin B5 (as d-calcium pantothenate)	10 mg	100%
Calcium (as Aquamin calcified mineral source red algae <i>Lithothamnion</i> sp. [whole plant], calcium ascorbate)	200 mg	15%
Iron (as ferrous bisglycinate)	28 mg	156%
Iodine (as potassium iodide)	150 mcg	100%
Magnesium (as magnesium oxide)	100 mg	22%
Zinc (as zinc glycinate)	15 mg	100%
Copper (as copper bisglycinate)	2 mg	100%
Sodium	10 mg	< 1%
DHA (docosahexaenoic acid) (Life's DHA S40-0400 algal oil)	200 mg	**
Orchard Fruits / Garden Veggies Powder Blend	100 mg	**
Spinach, pea, cabbage, cauliflower, apple, asparagus, broccoli, brussels sprout, cucumber, tomato, acai, banana, beet, blueberry, carrot, cherry, cranberry, grape, pineapple, prune, raspberry, strawberry		
Choline (as choline bitartrate)	10 mg	**
Inositol	10 mg	**

* Percent Daily Values are based on a 2,000 calorie diet.

** Daily Value not established.

Other Ingredients: Sunflower oil, modified food starch, carrageenan, glycerin, sorbitol, sunflower lecithin, candelilla wax, annatto color, purified water, natural flavors, sodium copper chlorophyllin.

(b) Nature's Way Prenatal Multi-Vitamin and Multi-Mineral:

Supplement Facts

Serving Size 2 Capsules

Servings Per Container 90

Amount Per Serving	% Daily Value
Vitamin A (91% as beta carotene [7,508 IU], 9% as retinyl acetate [742 IU])	8,250 IU 165%
Vitamin C (as calcium ascorbate)	100 mg 167%
Vitamin D (as cholecalciferol)	200 IU 50%
Vitamin E (as d-alpha tocopheryl)	100 IU 333%
Vitamin K (as phytonadione)	30 mcg 38%
Thiamin (as thiamin HCl)	5 mg 333%
Riboflavin (Vitamin B2)	5 mg 294%
Niacin (as niacinamide)	15 mg 75%
Vitamin B6 (as pyridoxine HCl)	25 mg 1,250%
Folic Acid	400 mcg 100%
Vitamin B12 (as cyanocobalamin)	25 mcg 416%
Biotin	50 mcg 17%
Pantothenic Acid (as d-calcium pantothenate)	25 mg 250%
Calcium (as carbonate/citrate)	250 mg 25%
Iron (as iron gluconate)	9 mg 50%
Iodine (as kelp powder)	25 mcg 17%
Magnesium (as aspartate/oxide)	125 mg 31%
Zinc (as zinc bisglycinate chelate)	10 mg 67%
Selenium (as L-selenomethionine)	50 mcg 71%
Copper (as amino acid chelate)	1 mg 50%
Manganese (as aspartate)	5 mg 250%
Molybdenum	50 mcg 71%
Potassium (as gluconate/chloride)	45 mg 1%
Kelp (whole thallus)	42 mg **

**Daily Value (DV) not established.

Recommendation: Pregnant/nursing women chew 3 gummies daily. If taking any medications, consult a healthcare professional before use. **Keep out of reach of children.**

Supplement Facts			Amount per 3 Gummies		% DV
Serving Size 3 Gummies Servings Per Container 25			Pantothenic Acid (B5) (as calcium d-pantothenate)		5 mg 50%
Amount per 3 Gummies			Iodine (as potassium iodide)		150 mcg 100%
% DV			Zinc (as zinc citrate)		3.75 mg 25%
Calories 30			Sodium		15 mg <1%
Total Carbohydrate 7 g			Orchard Fruits™ & Garden Veggies™ Powder Blend: Orange, Blueberry, Carrot, Plum, Pomegranate, Strawberry, Pear, Apple, Beet, Raspberry, Pineapple, Pumpkin, Cherry, Cauliflower, Grape, Banana, Cranberry, Açaí, Asparagus, Broccoli, Brussels Sprout, Cabbage, Cucumber, Pea, Spinach, Tomato		150 mg **
Sugars 5 g			Docosahexaenoic Acid (DHA) (from Algal microalgae oil)		75 mg **
Vitamin A (as retinyl palmitate) 4,000 IU			Choline (as choline bitartrate)		10 mg **
Vitamin C (ascorbic acid) 60 mg			†Percent Daily Values (DV) are based on a 2,000 calorie diet. **Daily Value not established.		
Vitamin D3 (as cholecalciferol) 600 IU					
Vitamin E (as d-alpha tocopheryl acetate) 30 IU					
Thiamin (B1) (as thiamin HCl) 850 mcg					
Riboflavin (B2) 1 mg					
Niacin (B3) (as niacinamide) 20 mg					
Vitamin B6 (as pyridoxine HCl) 3.75 mg					
Folic Acid (B9) 800 mcg					
Vitamin B12 (as cyanocobalamin) 12 mcg					
Biotin (B7) 300 mcg					

Other ingredients: organic tapioca syrup, cane sugar, pectin, citric acid, natural flavors, sodium citrate, elderberry color, fractionated coconut oil (non-hydrogenated), beeswax

(d) Nature's Way Completia® Prenatal Multi-Vitamin:

Supplement Facts		
Serving Size 2 Tablets Servings Per Container 120		
Per Serving Amount		% Daily Value
Calories	5	
Total Carbohydrate	<1 g	<1%*
Dietary Fiber	<1 g	3%*
Vitamin A (100% as beta carotene)	4,000 IU	50%
Providing (typical analysis):		
beta carotene	2,250 mcg	
gamma carotene	2.25 mcg	
trans beta carotene	2.15 mcg	
beta zeo carotene	0.45 mcg	
Vitamin C (as calcium ascorbate)	60 mg	100%
Vitamin D3 (as cholecalciferol)	200 IU	50%
Vitamin E (as d-alpha tocopheryl succinate)	15 IU	50%
Vitamin K (as phytonadione)	45 mcg	**
Thiamin (as thiamin mononitrate)	850 mcg	50%
Riboflavin (Vitamin B2)	1 mg	50%
Niacin (as niacinamide)	10 mg	50%
Vitamin B6 (as pyridoxine HCl)	1.25 mg	50%
Folic Acid	400 mcg	50%
Vitamin B12 (as cyanocobalamin)	4 mcg	50%
Biotin	150 mcg	50%
Pantothenic Acid (as d-calcium pantothenate)	5 mg	50%
Calcium (as carbonate, citrate, ascorbate)	360 mg	28%
Iron (as iron gluconate)	22.5 mg	125%
Iodine (from Pacific kelp powder)	75 mcg	50%
Magnesium (as citrate/oxide)	150 mg	33%
Zinc (as amino acid chelate)	7.5 mg	50%
Selenium (as L-selenomethionine)	12.5 mcg	**
Copper (as amino acid chelate)	1 mg	50%
Manganese (as amino acid chelate)	1 mg	**
Chromium (as polynicotinate)	25 mcg	**
Sodium	15 mg	**
Potassium (as amino acid chelate)	25 mg	**
DHA (docosahexaenoic acid (tuna))	25 mg	**
Red Raspberry (leaf)	25 mg	**
Dandelion (root)	25 mg	**
Nettle (leaf)	25 mg	**
Peppermint (leaf)	25 mg	**
Inositol	5 mg	**
Choline (as choline bitartrate)	2 mg	**
PABA (para aminobenzoic acid)	1 mg	**

* Percent Daily Values are based on a 2,000 calorie diet.
** Daily Value (DV) not established.

136. Defendants' Marketing of their Products' Folic Acid, along with Defendants falsely stating as "fact" that their Prenatal Vitamins contain a certain amount of Folic Acid, demonstrates their recognition of the importance of Folic Acid in the development of a baby in-utero.

137. Based on Defendants' decision to market the Prenatal Vitamins as containing a certain amount of Folic Acid, they had a duty to ensure that their statements were true and not misleading. As such, Defendants knew or should have known they were falsely Marketing the amount of Folic Acid in their Prenatal Vitamins.

138. Defendants' Marketing of the Prenatal Vitamins fails to accurately state that the Products actually contain, or have the risk of containing, less Folic Acid than is promised on the Products' labels, while also promoting the Products' inclusion of Folic Acid "for mom & developing baby[.]"

139. As a result of Defendants' false and misleading labeling, a reasonable consumer would have no reason to suspect the Prenatal Vitamins had a risk of containing less Folic Acid than promised on the label without conducting his or her own scientific tests or reviewing third party scientific testing of the Products.

B. Due to the Misrepresentations of the Defendants' Prenatal Vitamins, Defendants' Marketing is Misleading

140. At all times during the Class Period, Defendants knew or should have known that their Marketing was misleading. Defendants failed to disclose the correct amount of Folic Acid in their Prenatal Vitamins, even though Defendants touted their Products as a "complete formula" and a "premium formula" with "100% Daily Value 16 Vitamins & Minerals," and containing "High Potency Folic Acid."

141. Defendants assert that they conduct thorough testing of every ingredient on-site and are subject to legal and regulatory compliance regarding their manufacturing practices, standards which Defendants have "exceeded" for decades.⁸³

142. Defendants knew or should have known the Prenatal Vitamins contained or had a risk of containing less Folic Acid than promised on the Products' labels due to Defendants' purported manufacturing and testing procedures and supplier relationships. Defendants were aware of this risk and failed to disclose it to the Plaintiffs and the Class.

143. Defendants knew or should have known that women who are pregnant or may become pregnant who consume low amounts of Folic Acid are at higher risk of miscarrying and placing their babies at higher risk of developing NTDs, such as spina bifida.

⁸³ <https://www.naturesway.com/quality> (last accessed January 3, 2022).

1 144. Defendants knew or should have known that they owed consumers a duty of care
2 to ensure their Products either contained the amount of Folic Acid represented on the label, or
3 alternatively, truthfully represented the actual amount of Folic Acid in the Prenatal Vitamins.

4 145. Defendants knew or should have known they owed consumers a duty of care to
5 accurately disclose the amount of Folic Acid in the Prenatal Vitamins.

6 146. Defendants knew or should have known consumers purchased the Prenatal
7 Vitamins based on the reasonable expectation that Defendants manufactured the Prenatal Vitamins
8 to the highest standards. Based on this expectation, Defendants knew or should have known
9 consumers reasonably inferred that Defendants would hold the Prenatal Vitamins to the highest
10 standards for ensuring the labels accurately reflected the amount of Folic Acid contained in the
11 final Products.

12 147. The labels for Defendants' Prenatal Vitamins represent that the Products contain a
13 certain amount of Folic Acid. But Defendants' Products contain a different amount of Folic Acid
14 than is represented on their labels.

15 148. Despite the known risks of Folic Acid deficiency for women who are pregnant or
16 may become pregnant, Defendants have negligently, recklessly, and/or knowingly sold the
17 Prenatal Vitamins with labels that falsely asserted the Products contained an amount of Folic Acid
18 that they in fact did not contain.

19 149. Based on the foregoing, reasonable consumers, like Plaintiffs, would consider an
20 amount of Folic Acid that was deficient, or risked being deficient, to the amount stated on the
21 product label a material fact when considering what prenatal vitamin to purchase.

22 150. Defendants knew or should have known that monitoring and accurately reporting
23 the amount of Folic Acid in their Prenatal Vitamins was not only important but critical.

24 151. Defendants also knew or should have known that adequately representing the
25 amount of Folic Acid in the Prenatal Vitamins was likewise important to their health-conscious
26 consumers, like Plaintiffs and Class members.

152. Defendants knew or should have known they could control the amount of Folic Acid in the Prenatal Vitamins by monitoring its presence and adjusting any formulation to increase the amount of Folic Acid in their Products.

153. Defendants knew or should have known failure to adequately report the amount of Folic Acid in the Prenatal Vitamins continued throughout the Class Period.

154. Defendants' Marketing was misleading due to their failure to disclose the true amount of Folic Acid in the Prenatal Vitamins.

155. Defendants knew or should have known consumers paid a price premium and expected Defendants to represent the true amount of Folic Acid in the Prenatal Vitamins.

Critical Ingredient: Folic Acid

156. Folic Acid, a dietary Folate equivalent ("DFE"), is crucial for brain function, and is especially important during pregnancy when cells and tissues are growing rapidly.⁸⁴ Studies have shown that proper allowances of Folic Acid can help prevent miscarriage, birth defects, NTDs, including spina bifida (which affects the spine) and anencephaly (which affects the brain), as well as skull malformation.⁸⁵ Therefore, Folic Acid consumption is critical for prenatal health.

157. Folic Acid is a synthetic form of Folate. Folate is found naturally in foods such as certain vegetables, fruits, and nuts; however, it is difficult for humans to consume the recommended daily amount of Folate from diet alone.⁸⁶ Moreover, the human body absorbs more Folic Acid from fortified foods and supplements than from Folate naturally found in foods.⁸⁷

⁸⁴ NIH, Office of Dietary Supplements, "Folate Fact Sheet for Health Professionals," updated March 29, 2021, available at <https://ods.od.nih.gov/factsheets/Folate-HealthProfessional/> (last accessed January 3, 2022) ("Folate Fact Sheet for Health Professionals").

⁸⁵ *Folate Fact Sheet for Health Professionals, supra*.

⁸⁶ U.S. Department of Health & Human Services, Office of Women's Health, "Folic Acid," last updated April 1, 2019, available at <https://www.womenshealth.gov/a-z-topics/folic-acid#:~:text=Folate%20is%20found%20naturally%20in%20some%20foods%2C%20including%20spinach%2C%20nuts,food%20has%20added%20folic%20acid> (last accessed January 3, 2022) ("HHS Folic Acid").

⁸⁷ NIH, Office of Dietary Supplements, "Folate Fact Sheet for Consumers," Updated March 22, 2021, available at <https://ods.od.nih.gov/factsheets/Folate-Consumer/> (last accessed January 3, 2022).

Therefore, Folic Acid is used in supplements to help humans meet their nutritional needs.⁸⁸ Folic Acid supplements are specifically recommended for women who are pregnant or may become pregnant because of the important role of Folic Acid in promoting prenatal health.

158. Underscoring the importance of Folate to the nutrition of women of a childbearing age to a healthy pregnancy, and the difficulty for most women to get the daily recommended amount of Folate through diet alone,⁸⁹ in January 1998, the FDA required food manufacturers to add Folic Acid to commonly consumed foods, including breads, cereals, rice, pasta, and other grains, to decrease the risk of NTDs.⁹⁰

159. Three thousand pregnancies every year in the U.S. are affected by NTDs.⁹¹ NTDs are not only debilitating for the baby and family, but also to the health care system. For example, “the total lifetime direct cost of care for a child born with spina bifida in the U.S. is estimated to be \$791,900.”⁹² However, with Folic Acid fortification, NTD prevalence decreased by thirty-six percent in the U.S.⁹³

160. Therefore, Folic Acid is vital for women to consume prior to and during pregnancy to support prenatal health.⁹⁴ The less Folic Acid a woman who is pregnant or may become pregnant consumes, the more likely the baby will develop NTDs.⁹⁵

⁸⁸ *Id.*

⁸⁹ *CDC Folic Acid, supra.*

⁹⁰ Harvard School of Public Health, The Nutrition Source, “Folate (Folic Acid) – Vitamin B9,” available at <https://www.hsph.harvard.edu/nutritionsource/folic-acid/> (last accessed January 3, 2022).

⁹¹ CDC, “Folic Acid: Birth Defects COUNT,” last reviewed November 9, 2017, available at <https://www.cdc.gov/ncbddd/birthdefectscount/data.html> (last accessed January 3, 2022).

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *CDC Folic Acid, supra.*

⁹⁵ See, e.g., *Folate Fact Sheet for Health Professionals, supra* (explaining that due to the importance of consuming Folic Acid prior to and during pregnancy, the National Institutes of Health recommends that women of reproductive age who could become pregnant consume 400 mcg of a DFE such as Folic Acid daily, and that women who are pregnant consume 600 mcg DFE daily); and HHS Office on Women’s Health, “Folic Acid,” last updated April 1, 2019, available at <https://www.womenshealth.gov/a-z-topics/folic-acid> (last accessed January 3, 2022) (stating

1 161. Defendants' labels for the Prenatal Vitamins state that the Products contain a certain
2 amount of Folic Acid.

3 162. However, at all times during the Class Period, Defendants did not truthfully
4 represent the amount of Folic Acid in the Prenatal Vitamins.

5 163. Defendants knew or should have known consumers reasonably expected them to
6 truthfully report the amount of Folic Acid contained in the Prenatal Vitamins.

7 164. Defendants knew or should have known the amount of Folic Acid contained in their
8 Prenatal Vitamins was inconsistent with their Marketing. The Products contained an amount of
9 Folic Acid inconsistent with the amount Defendants represented on the labels.

10 165. Defendants knew or should have known that consumers expected them to ensure
11 the amount of Folic Acid in their Products complied with their Marketing.

12 166. Defendants knew or should have known, through their thorough testing, the
13 accurate amount of Folic Acid contained in the Prenatal Vitamins, yet failed to represent that
14 amount.

15 167. Defendants' above-referenced statements and representations are false, misleading,
16 and crafted to deceive the public as they create an image that the Prenatal Vitamins are "complete"
17 and "premium" with "100 % Daily Value 16 Vitamins & Minerals," and contain "High Potency
18 Folic Acid," are "Advanced Prenatal for Mom & Developing Baby," and support "healthy
19 brain/spinal cord development."

20 168. Moreover, reasonable consumers, such as Plaintiffs and Class members, would
21 have no reason to doubt Defendants' statements regarding the amount of the Folic Acid in their
22 Prenatal Vitamins. Defendants' misrepresentations and false statements of fact regarding the
23 amount of Folic Acid in the Prenatal Vitamins coupled with their promotion of the Products
24 nutritious value were intended to and did, in fact, cause consumers like Plaintiffs and the members
25 of the Class, to purchase products they would not have if they had known the Prenatal Vitamins

26 _____
27 that the HHS Office on Women's Health, in accordance with the U.S. Preventive Services Task
28 Force Final Recommendation Statement, suggests that women who may become pregnant or are
pregnant need 400 to 800 mcg of Folic Acid daily).

1 contained or risked containing a deficient amount of Folic Acid as compared to the amount
2 promised on the label.

3 **C. Defendants' Marketing Misled and Deceived Consumers as to the quantity of**
4 **ingredients in their Prenatal Vitamins, including the amount of Folic Acid**

5 169. As a result of Defendants' wrongful Marketing, which includes misleading,
6 deceptive, unfair, and false statements, Defendants have generated substantial sales of the Prenatal
7 Vitamins.

8 170. Defendants' wrongful Marketing, which includes misleading, deceptive, unfair,
9 and false representations, allowed them to capitalize on, and reap enormous profits from,
10 consumers who paid the price premium for the Prenatal Vitamins.

11 171. Defendants' Marketing failed to represent to consumers that their Prenatal Vitamins
12 contained or risked containing less Folic Acid than the amount stated on the labels.

13 172. Although Defendants misleadingly cause consumers to believe their Prenatal
14 Vitamins provide an amount of Folic Acid as specified on the label through their Marketing and
15 false labeling, the Prenatal Vitamins, in fact, do not contain the amount of Folic Acid they claim,
16 which is material information to reasonable consumers.

17 173. Plaintiffs' counsel had the Defendants' Prenatal Vitamins tested and the tests
18 confirmed that the Defendants misrepresented the quantity of Folic Acid in their Products.

19 174. The Alive!® Complete Prenatal Multi-Vitamin (60 count) contained 13.14 µg⁹⁶ per
20 serving, and another test showed it contained 741.25 µg per serving. Not only is this a wide
21 discrepancy from sample to sample, but it also is less than the amount promised on the Products'
22 label.

23 175. Therefore, Defendants' Marketing states the Prenatal Vitamins contain amounts of
24 Folic Acid that is different than the amount their Products actually contain.

25 176. Based on Defendants' Marketing and mislabeling, a reasonable consumer would
26 not suspect the amount of Folic Acid in the Product to be different than the amount indicated on

27 _____
28 ⁹⁶ Micrograms may be reflected as "mcg" or "µg." Plaintiffs' tests results were listed as µg.

1 the Product label, nor would a reasonable consumer be able to detect the actual amount of Folic
2 Acid in the Prenatal Vitamins without conducting his or her own scientific tests or reviewing
3 scientific testing conducted on the Products.

4 177. Reasonable consumers must and do rely on Defendants to honestly report the
5 amount and value of Folic Acid contained in their Prenatal Vitamins.

6 178. In light of Defendants' Marketing, Defendants knew or should have known they
7 misrepresented the amount of Folic Acid on the label of their Nature's Way products.

8 179. Defendants intended for consumers to rely on their Marketing, and reasonable
9 consumers did in fact so rely.

10 180. Defendants had a duty to ensure the Prenatal Vitamins were as they were
11 represented and not deceptively, misleadingly, unfairly, and falsely marketed.

12 181. Pursuant to the foregoing, Defendants' Marketing is deceptive, misleading, unfair,
13 and false to Plaintiff and other consumers, including under the consumer protection laws of
14 California.

15 182. Defendants acted negligently, recklessly, unfairly, and/or intentionally with their
16 deceptive, misleading, unfair, and false Marketing.

17 **DEFENDANTS' MISLEADING MARKETING VIOLATES 21 U.S.C. §343**

18 183. Defendants' misleading statements to consumers that their Prenatal Vitamins are
19 natural, nutritious, and nurturing of a healthy pregnancy violate 21 U.S.C. §343, which provides
20 that dietary supplements are misbranded when they contain false statements on their labels.
21

22 184. Defendants violated 21 U.S.C. §343 by not accurately detailing that the Prenatal
23 Vitamins contain, or risk containing, Heavy Metals. Defendants misleading Marketing includes
24 false statements that the Prenatal Vitamins are "premium quality," "premium formula,"
25 "complete," "advanced prenatal," "smarter prenatal," and support both "mom & developing baby"
26 and "healthy brain/spinal cord development." These statements are false as the Prenatal Vitamins
27 contain or risk containing undisclosed levels of Heavy Metals.
28

185. Defendants violated 21 U.S.C. §343 by falsely stating that the Prenatal Vitamins contained an amount of Folic Acid that was different than the amount the Products actually contained. These statements are false as the Prenatal Vitamins contained or risked containing a deficient amount of Folic Acid than was promised on the label.

186. Accordingly, Defendants' mislabeling of their Prenatal Vitamins, which forms the basis of this lawsuit, constitutes a violation of 21 U.S.C. §343.

**DEFENDANTS' STATEMENTS AND OMISSIONS VIOLATE THE
CURRENT GOOD MANUFACTURING PRACTICES GUIDELINES**

187. By law and regulation, supplement manufacturers like Defendants are required to comply with the current good manufacturing practices ("CGMP"). 21 CFR §111.

188. The Dietary Supplement ("DS") CGMP rule stated at 21 CFR §111 requires persons who manufacture, package, label or hold a dietary supplement to establish and comply with current good manufacturing practice to ensure the quality of the product and that the product is packaged and labeled as specified in the master manufacturing record.

189. Despite their "manufacturing excellence" and designation as a Good Manufacturing Practices facility by NSF, Defendants violated the DS CGMP rule by negligently, recklessly, and/or intentionally incorrectly claiming that their Prenatal Vitamins are natural, nutritious, and nurturing of a healthy pregnancy, and by not accurately detailing that their Products contain or risk containing Heavy Metals, with the exception that one Product did "not contain harmful levels of Mercury," and by falsely representing that the Products contained an amount of Folic Acid that was different than the amount the Product actually contained.

190. Accordingly, Defendants' mislabeling of their Prenatal Vitamins, which forms the basis of this lawsuit, constitutes a violation of the DS CGMP rule stated at 21 CFR §111.

DEFENDANTS' STATEMENTS AND OMISSIONS VIOLATE CALIFORNIA LAWS

191. California law is designed to ensure that a company's claims about its products are truthful and accurate.

192. Defendants violated California law by negligently, recklessly, and/or intentionally incorrectly claiming that their Prenatal Vitamins are natural, nutritious, and nurturing of a healthy pregnancy, and are of “premium quality” and “premium formula” to support “mom & developing baby,” and by not disclosing the presence or risk of Heavy Metals in the Products.

193. Defendants violated California law by negligently, recklessly, and/or intentionally incorrectly claiming that the Prenatal Vitamins are natural, nutritious, and nurturing of a healthy pregnancy and contain “High Potency Folic Acid” and are a “complete formula” that support “healthy brain/spinal cord development,” and by not accurately stating that the amount of Folic Acid in their Products is not the amount represented on the Product label.

194. Defendants’ Marketing has been sufficiently lengthy in duration, and widespread in dissemination, that it would be unrealistic to require Plaintiffs to plead relying upon each advertised misrepresentation.

195. Defendants have engaged in this long-term advertising campaign to convince potential customers that their Prenatal Vitamins were natural, nutritious, and nurturing of a healthy pregnancy, and did not contain or risk containing harmful ingredients, such as Heavy Metals, and contained the amount of Folic Acid that was promised on the label.

PLAINTIFFS’ RELIANCE WAS REASONABLE AND FORESEEN BY DEFENDANTS

196. Plaintiffs reasonably relied on Defendants’ claims, warranties, representations, advertisements, and other Marketing concerning the particular qualities and benefits of the Prenatal Vitamins.

197. Plaintiff read and relied upon the labels and packaging of the Prenatal Vitamins when making her purchasing decisions. Had she known Defendants did not disclose the presence or risk of Heavy Metals in their packaging, she would not have purchased them. Had she known the Prenatal Vitamins contained a different amount of Folic Acid than the label promised, she would not have purchased them.

198. A reasonable consumer would consider the labeling of a product when deciding whether purchase a product. Here, Plaintiff relied on the specific statements and omissions on the Prenatal Vitamins labeling that led her to believe they were natural, nutritious, and nurturing of a

1 healthy pregnancy, and free of the presence or risk of Heavy Metals, and that she was consuming
2 the amount of Folic Acid as promised on the label.

3 **DEFENDANTS' KNOWLEDGE AND NOTICE OF ITS BREACHES OF**
4 **THEIR EXPRESS AND IMPLIED WARRANTIES**

5 199. Defendants had sufficient notice of their breaches of express and implied
6 warranties. Defendants have, and had, exclusive knowledge of the physical and chemical make-
7 up of the Prenatal Vitamins through their self-declared testing and manufacturing practice, and
8 robust supplier relationships.

9 200. Moreover, Defendants were put on notice by the 2008 FDA Survey about the
10 inclusion of Heavy Metals, specifically Lead, in one their women's and children's vitamins,
11 including a prenatal vitamin, and they also acknowledge the presence of non-harmful levels of
12 Mercury in one Product.

13 201. Defendants did not change their packaging or labels to include any disclaimer that
14 the Prenatal Vitamins contained or may contain any levels of Heavy Metals, with the exception of
15 acknowledging the presence an undisclosed level of Mercury in one of their Products. Defendants
16 also did not correct their packaging or labels to state the accurate amount of Folic Acid in the
17 Prenatal Vitamins.

18 **PRIVITY EXISTS WITH PLAINTIFFS AND THE PROPOSED CLASS**

19 202. Defendants knew that consumers such as Plaintiffs and the proposed Class would
20 be the end purchasers of the Prenatal Vitamins and the target of their Marketing.

21 203. Defendants intended that the warranties, advertising, labeling, statements, and
22 representations would be considered by the end purchasers of the Prenatal Vitamins, including
23 Plaintiffs and the proposed Class.

24 204. Defendants directly marketed to Plaintiffs and the proposed Class through
25 statements on their website, social media, labeling, advertising, and packaging.

26 205. Plaintiff and the proposed Class are the intended beneficiaries of the expressed and
27 implied warranties.
28

CLASS ACTION ALLEGATIONS

206. Plaintiff brings this action individually and on behalf of the following Class pursuant to Rules 23(a) and 23(b)(2) and (3) of the Federal Rules of Civil Procedure:

All persons residing in the United States or its territories who, during the maximum period of time permitted by law, purchased Nature's Way Prenatal Vitamins (specifically, Nature's Way Alive!® Complete Prenatal Multi-Vitamin; Nature's Way Prenatal Multi-Vitamin and Multi-Mineral; Nature's Way Alive!® Prenatal Gummy; and Nature's Way Completia® Prenatal Multi-Vitamin), manufactured by Defendants, Schwabe North America, Inc., and Nature's Way Brands, LLC (the "Class").⁹⁷

207. Excluded from the Class are Defendants, any parent companies, subsidiaries, and/or affiliates, officers, directors, legal representatives, employees, co-conspirators, all governmental entities, and any judge, justice, or judicial officer presiding over this matter.

208. Also excluded from the Class are any individuals or businesses who purchased the Nature's Way Prenatal Vitamin products for the purpose of resale.

209. This action is brought and may be properly maintained as a class action. There is a well-defined community of interests in this litigation and the members of the Class are easily ascertainable.

210. The members in the proposed Class are so numerous that individual joinder of all members is impracticable, and the disposition of the claims of all Class members in a single action will provide substantial benefits to the parties and Court.

211. Questions of law and fact common to Plaintiff and the Class include, but are not limited to, the following:

- (a) whether Defendants owed a duty of care;
- (b) whether Defendants knew or should have known that the Prenatal Vitamins contained or risked containing Heavy Metals;

⁹⁷ Plaintiffs reserve the right to amend this definition as necessary in accordance with applicable Federal and California law.

1 (c) whether Defendants represented and continue to represent that the Prenatal
2 Vitamins are natural, nutritious, and nurturing of a healthy pregnancy;

3 (d) whether Defendants represented and continue to represent that the Prenatal
4 Vitamins contain a different amount of Folic Acid than is in fact contained in the Products;

5 (e) whether Defendants omitted the risk of exposure to Heavy Metals and/or
6 the presence of Heavy Metals in their Products, and/or made misrepresentations regarding quality
7 control of their Products;

8 (f) whether Defendants misrepresented the quantity or amount of the
9 ingredients, including Folic Acid, as stated on the label, and/or misrepresented the quantity or
10 amount of the ingredients, including Folic Acid, in the formulation of their Products;

11 (g) whether Defendants represented and continues to represent that the
12 manufacturing of the Prenatal Vitamins is subjected to rigorous quality standards;

13 (h) whether Defendants' representations in advertising, warranties, packaging,
14 and/or labeling are false, deceptive, and misleading;

15 (i) whether those representations are likely to deceive a reasonable consumer;

16 (j) whether Defendants had knowledge that those representations were false,
17 deceptive, and misleading;

18 (k) whether Defendants continue to disseminate those representations despite
19 knowledge that the representations are false, deceptive, and misleading;

20 (l) whether a representation that a Product is natural, nutritious, and nurturing
21 of a healthy pregnancy, and does not contain or risk containing levels of Heavy Metals is material
22 to a reasonable consumer;

23 (m) whether a representation that a Product actually provides the amount of
24 Folic Acid stated on the label is material to a reasonable consumer;

25 (n) whether Defendants' Marketing of the Prenatal Vitamins are likely to
26 mislead, deceive, confuse, or confound consumers acting reasonably;

27 (o) whether Defendants violated California Business & Professions Code
28 sections 17200, *et seq.*;

1 (p) whether Defendants violated California Business & Professions Code
2 sections 17500, *et seq.*;

3 (q) whether Defendants violated California Civil Code sections 1750, *et seq.*;

4 (r) whether Defendants violated 21 USC §343;

5 (s) whether Defendants violated the Good Manufacturing Practices Guidelines;
6 and

7 (t) whether Plaintiffs and the members of the Class are entitled to declaratory
8 and injunctive relief.

9 212. Defendants engaged in a common course of conduct giving rise to the legal rights
10 sought to be enforced by Plaintiffs individually and on behalf of the other members of the Class.
11 Identical statutory violations and business practices and harms are involved. Individual questions,
12 if any, are not prevalent in comparison to the numerous common questions that dominate this
13 action.

14 213. Plaintiffs' claims are typical of those of the members of the Class in that they are
15 based on the same underlying facts, events, and circumstances relating to Defendants' conduct.

16 214. Plaintiffs will fairly and adequately represent and protect the interests of the Class,
17 have no interests incompatible with the interests of the Class, and have retained counsel competent
18 and experienced in class action, consumer protection, and false advertising litigation.

19 215. Class treatment is superior to other options for resolution of the controversy
20 because the relief sought for each member of the Class is small such that, absent representative
21 litigation, it would be infeasible for members of the Class to redress the wrongs done to them.

22 216. Questions of law and fact common to the Class predominate over any questions
23 affecting only individual members of the Class.

24 217. As a result of the foregoing, class treatment is appropriate.

25 **COUNT I**

26 **(Negligent Misrepresentation Against Defendants on Behalf of the Class)**

27 218. Plaintiffs incorporate by reference and reallege each and every allegation contained
28 above, as though fully set forth herein.

1 219. Plaintiffs reasonably placed their trust and reliance on Defendants' representations
2 that the Prenatal Vitamins were as marketed to them and the Class, and were natural, nutritious,
3 and nurturing of a healthy pregnancy, did not contain undisclosed levels of Heavy Metals, and
4 contained the amount of Folic Acid as stated on the Product label.

5 220. Because of the relationship between the parties, Defendants owed Plaintiffs and the
6 Class a duty to use reasonable care in the formulation, testing, manufacturing, Marketing,
7 distribution, and sale of the Prenatal Vitamins, and to impart correct and reliable disclosures and
8 statements concerning the presence of Heavy Metals and the amount of Folic Acid in the Prenatal
9 Vitamins, or based on upon their superior knowledge of the physical and chemical make-up of the
10 Products, having spoken, to say enough to not be misleading.

11 221. Defendants breached their duty to Plaintiffs and the Class by formulating, testing,
12 manufacturing, advertising, Marketing, distributing, and selling products to Plaintiffs and the Class
13 that did not have the ingredients, qualities, characteristics, and suitability for consumption as
14 marketed by Defendants and by providing false, misleading, and/or deceptive information
15 regarding the nature of the Prenatal Vitamins.

16 222. Defendants knew or should have known the ingredients, qualities, and
17 characteristics of the Prenatal Vitamins were not as advertised or suitable for their intended use
18 (consumption by women who are pregnant or may become pregnant), and were otherwise not as
19 warranted and represented.

20 223. Plaintiffs and the Class reasonably and justifiably relied upon the information
21 supplied to them by the Defendants. A reasonable consumer would have relied on Defendants'
22 warranties, statements, representations, advertising, packaging, labeling, and other Marketing as
23 to the quality, make-up, and ingredients of the Prenatal Vitamins.

24 224. As a direct and proximate result of Defendants' misrepresentations, Plaintiffs and
25 the Class suffered actual damages in that they purchased the Prenatal Vitamins that were worth
26 less than the price paid and that they would not have purchased at all had they known they
27 contained or may contain Heavy Metals that do not conform to the Products' labels, packaging,
28

1 advertising, and statements, and did not contain the amount of Folic Acid promised on the
2 Products' labels and packaging.

3 225. Defendants failed to use reasonable care in their communications and
4 representations to Plaintiffs and the Class, especially in light of their knowledge of the presence
5 of Heavy Metals in the Prenatal Vitamins, and the actual amount of Folic Acid in the Products,
6 and the importance consumers place on ingredients when deciding whether to purchase products
7 such as the Prenatal Vitamins.

8 226. By virtue of Defendants' negligent misrepresentations, Plaintiffs and the Class have
9 been damaged in an amount to be proven at trial, or alternatively, seek rescission and disgorgement
10 under this Count.

11 **COUNT II**

12 **(Violations of California's Consumer Legal Remedies Act, California Civil Code §§1750,
13 *Et Seq.*, Against Defendants on Behalf of the Class)**

14 227. Plaintiffs incorporate by reference and reallege each and every allegation contained
15 above, as though fully set forth herein.

16 228. Plaintiffs and each proposed Class member is a "consumer," as that term is defined
17 in California Civil Code §1761(d).

18 229. The Prenatal Vitamins are "goods," as that term is defined in California Civil Code
19 §1761(a).

20 230. Defendants are a "person" as that term is defined in California Civil Code §1761(c).

21 231. Plaintiffs' and each proposed Class member's purchase of Defendants' Products
22 constituted a "transaction" as that term is defined in California Civil Code §1761(e).

23 232. Defendants' conduct alleged herein violates the following provisions of
24 California's Consumer Legal Remedies Act ("CLRA"):

25 (a) California Civil Code §1770(a)(5), by negligently, recklessly, and/or
26 intentionally representing that the Prenatal Vitamins are natural, nutritious, and nurturing of a
27 healthy pregnancy, by failing to disclose levels of Heavy Metals in the Prenatal Vitamins, and by
28 representing that the Products contained an amount of Folic Acid that they, in fact, did not.

1 (b) California Civil Code §1770(a)(7), by negligently, recklessly, and/or
2 intentionally representing that the Prenatal Vitamins were of a particular standard, quality, or
3 grade, when they were of another;

4 (c) California Civil Code §1770(a)(9), by negligently, recklessly, and/or
5 intentionally advertising the Prenatal Vitamins with intent not to sell them as advertised; and

6 (d) California Civil Code §1770(a)(16), by representing that the Prenatal
7 Vitamins have been supplied in accordance with previous representations when they have not.

8 233. As a direct and proximate result of these violations, Plaintiffs and the Class have
9 been harmed, and that harm will continue unless Defendants are enjoined from using the
10 misleading Marketing described herein in any manner in connection with the advertising and sale
11 of the Prenatal Vitamins.

12 234. Plaintiffs seek an award of attorneys' fees pursuant to, inter alia, California Civil
13 Code §1780(e) and California Code of Civil Procedure §1021.5.

14 **COUNT III**

15 **(Violations of California False Advertising Law, California Business & Professions
16 Code §§17500, *Et Seq.*, Against Defendants on Behalf of the Class)**

17 235. Plaintiffs incorporate by reference and reallege each and every allegation contained
18 above, as though fully set forth herein.

19 236. California's False Advertising Law prohibits any statement in connection with the
20 sale of goods "which is untrue or misleading." Cal. Bus. & Prof. Code §17500.

21 237. As set forth herein, Defendants' claims that the Prenatal Vitamins are natural,
22 nutritious, and nurturing of a healthy pregnancy are literally false and likely to deceive the public.

23 238. Defendants' claims that the Prenatal Vitamins are natural, nutritious, and nurturing
24 of a healthy pregnancy are untrue or misleading, as is failing to disclose the presence or risk of
25 levels of Heavy Metals in the Products, and stating that the Products provided an amount of Folic
26 Acid that they, in fact, did not.

27 239. Defendants knew, or reasonably should have known, that all these claims were
28 untrue or misleading.

240. Defendants' conduct is ongoing and continuing, such that prospective injunctive relief is necessary, especially given Plaintiffs' desire to purchase these products in the future if she can be assured that, so long as the Prenatal Vitamins are as advertised: natural, nutritious, and nurturing of a healthy pregnancy, do not contain or risk containing Heavy Metals, and contain the amount of Folic Acid as promised on the Product label.

241. Plaintiffs and members of the Class are entitled to injunctive and equitable relief, and restitution in the amount they spent on the Prenatal Vitamins.

COUNT IV

(Violations of the Unfair Competition Law, California Business & Professions Code §§17200, *Et Seq.*, Against Defendants on Behalf of the Class)

242. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.

243. The Unfair Competition Law prohibits any "unlawful, unfair or fraudulent business act or practice." Cal. Bus. & Prof. Code §17200.

Fraudulent

244. Defendants' statements that the Prenatal Vitamins are natural, nutritious, and nurturing of a healthy pregnancy are literally false and likely to deceive the public, as is Defendants' failing to disclose the presence or risk of Heavy Metals in the Prenatal Vitamins, and that their Products contain an amount of Folic Acid that, in fact, they do not.

Unlawful

245. As alleged herein, Defendants have advertised the Prenatal Vitamins with false or misleading claims, such that Defendants' actions as alleged herein violate at least the following laws:

- (a) The CLRA, California Business & Professions Code §§1750, et seq.;
- and
- (b) The False Advertising Law, California Business & Professions Code §§17500, et seq.

Unfair

246. Defendants' conduct with respect to the labeling, packaging, advertising, Marketing, and sale of the Prenatal Vitamins is unfair because Defendants' conduct was immoral, unethical, unscrupulous, or substantially injurious to consumers and the utility of their conduct, if any, does not outweigh the gravity of the harm to their victims.

247. Defendants' conduct with respect to the labeling, packaging, advertising, Marketing, and sale of the Prenatal Vitamins is also unfair because it violates public policy as declared by specific constitutional, statutory, or regulatory provisions, including, but not limited to, the False Advertising Law and the CLRA.

248. Defendants' conduct with respect to the labeling, packaging, advertising, Marketing, and sale of the Prenatal Vitamins is also unfair because the consumer injury is substantial, not outweighed by benefits to consumers or competition, and not one that consumers themselves can reasonably avoid.

249. In accordance with California Business & Professions Code §17203, Plaintiff seeks an order enjoining Defendants from continuing to conduct business through fraudulent or unlawful acts and practices and to commence a corrective advertising campaign. Defendants' conduct is ongoing and continuing, such that prospective injunctive relief is necessary.

250. On behalf of herself and the Class, Plaintiffs also seek an order for the restitution of all monies from the sale of the Prenatal Vitamins, which were unjustly acquired through acts of fraudulent, unfair, or unlawful competition.

COUNT V

**(Breach of Express Warranty, California Commercial Code §2313,
Against Defendants on Behalf of the Class)**

251. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.

252. Defendants marketed and sold the Prenatal Vitamins into the stream of commerce with the intent that the Products would be purchased by Plaintiffs and the Class.

1 253. As set forth herein, Defendants made express representations to Plaintiffs and the
2 Class that the Prenatal Vitamins were natural, nutritious, and nurturing of a health pregnancy.

3 254. Defendants made these express warranties regarding the Prenatal Vitamins quality,
4 ingredients, and fitness for consumption in writing through their website, social media, advertising,
5 and Marketing materials, and on the Prenatal Vitamins packaging and labels. These express
6 warranties became part of the basis of the bargain Plaintiffs and the Class entered into upon
7 purchasing the Products.

8 255. Defendants' advertisements, warranties, and representations were made in
9 connection with the sale of the Prenatal Vitamins to Plaintiffs and the Class. Plaintiffs and the
10 Class relied on Defendants' advertisements, warranties, and representations regarding the Prenatal
11 Vitamins in deciding whether to purchase Defendants' Products. Such promises became part of
12 the basis of the bargain between the parties, and thus constituted express warranties.

13 256. On the basis of these express warranties, Defendants sold to Plaintiffs and the Class
14 members the Prenatal Vitamins.

15 257. Defendants knowingly breached the express warranties in that they are not natural,
16 nutritious, and nurturing of a healthy pregnancy, as the Prenatal Vitamins:

17 (a) contain or risk containing undisclosed levels of Heavy Metals; and

18 (b) do not contain the amount of Folic Acid promised on the Product label.

19 258. Defendants were on notice of this breach as they have, and had, exclusive
20 knowledge of the physical and chemical make-up of the Prenatal Vitamins, they are required to
21 comply with the law and regulation, and they were cited in the 2008 FDA Survey that identified
22 vitamins, including prenatal vitamins, that contain Lead.

23 259. Privity exists because Defendants expressly warranted to Plaintiffs and the Class
24 that the Prenatal Vitamins were natural, nutritious, and nurturing of a healthy pregnancy, and by
25 failing to disclose levels of Heavy Metals and misrepresenting the amount of Folic Acid in the
26 Products.

27 260. As a direct and proximate result of Defendants' breaches of its express warranties,
28 Plaintiffs and the Class sustained damages as they purchased the Prenatal Vitamins that were worth

1 less than the price paid and they would not have purchased at all had they known the Prenatal
2 Vitamins contained or may contain undisclosed levels of Heavy Metals and that they contained a
3 different amount of Folic Acid than was stated on the Product labels.

4 261. Plaintiffs, on behalf of themselves and the Class, seeks actual damages, injunctive
5 and declaratory relief, attorneys' fees, costs, and any other just and proper relief available under
6 the laws.

7 **COUNT VI**
8 **(Breach of Implied Warranty of Merchantability, California Commercial Code §2314,**
9 **Against Defendants on Behalf of the Class)**

10 262. Plaintiffs incorporate by reference and reallege each and every allegation
11 contained above, as though fully set forth herein.

12 263. Defendants are merchants engaging in the sale of goods to Plaintiffs and the Class
13 members.

14 264. There was a sale of goods from Defendants to Plaintiffs and the Class members.

15 265. As set forth herein, Defendants manufactured or supplied the Products, and prior
16 to the time the Products were purchased by Plaintiffs and members of the Class, Defendants
17 impliedly warranted to them that the Prenatal Vitamins were of merchantable quality, fit for their
18 ordinary use, and conformed to the promises and affirmations of fact made on the Products'
19 packages and labels, including that the Products were natural, nutritious, and nurturing of a healthy
20 pregnancy, and failing to disclose levels of Heavy Metals and stating the Products contained an
21 amount of Folic Acid that they did not.

22 266. Plaintiffs and the Class relied on Defendants' promises and affirmations of fact
23 when they purchased the Prenatal Vitamins.

24 267. Contrary to these representations and warranties, the Prenatal Vitamins were not fit
25 for their ordinary use, consumption by women who are pregnant or may become pregnant, and did
26 not conform to Defendants' advertisements, warranties, and representations in that they are not
27 natural, nutritious, and nurturing of a healthy pregnancy as they:

28 (a) contain or risk containing undisclosed levels of Heavy Metals; and

1 (b) do not contain the amount of Folic Acid promised on the Product label.

2 268. These promises became part of the basis of the bargain between the parties and thus
3 constitute implied warranties.

4 269. Defendants breached the implied warranties by selling Products that failed to
5 conform to the promises or affirmations of fact made on the packaging or label, as each Product
6 contained or risked containing Heavy Metals that do not conform to the packaging and
7 misrepresented the quantity or amount of the ingredients, including Folic Acid, stated on the label.

8 270. Defendants were on notice of this breach as they were aware of the levels of Heavy
9 Metals and actual amount of Folic Acid in the Products as they have, and had, exclusive knowledge
10 of the physical and chemical make-up of the Prenatal Vitamins, they are required to comply with
11 the law and regulation, and they were cited in the 2008 FDA Survey that identified vitamins,
12 including prenatal vitamins, that contain Lead.

13 271. Privity exists because Defendants impliedly warranted to Plaintiffs and the Class
14 members through the warranting, packaging, advertising, Marketing, and labeling that the Prenatal
15 Vitamins were natural, nutritious, and nurturing of a healthy pregnancy, and by failing to disclose
16 levels or the risk of levels of Heavy Metals and misrepresenting the amount of Folic Acid in the
17 Products.

18 272. As a direct and proximate result of Defendants' conduct, Plaintiffs and the Class
19 have suffered actual damages in that they have purchased the Prenatal Vitamins that are worth less
20 than the price they paid and that they would not have purchased at all had they known the presence
21 or risk of Heavy Metals in the Products and that the Products contained, or risked containing, a
22 deficient amount of Folic Acid as compared to the amount stated on the label.

23 273. Plaintiffs and the Class seek actual damages, injunctive and declaratory relief,
24 attorneys' fees, costs, and any other just and proper relief available thereunder for Defendants'
25 failure to deliver goods conforming to its implied warranties and resulting breach.

COUNT VII
(Unjust Enrichment Against Defendants on Behalf of the Class)

274. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.

275. Substantial benefits have been conferred on Defendants by Plaintiffs and the Class through the purchase of the Prenatal Vitamins. Defendants knowingly and willingly accepted and enjoyed these benefits.

276. Defendants either knew or should have known that the payments rendered by Plaintiffs were given and received with the expectation that the Prenatal Vitamins would have the qualities, characteristics, ingredients, and suitability for consumption represented and warranted by Defendants. As such, it would be inequitable for Defendants to retain the benefit of the payments under these circumstances.

277. Defendants' acceptance and retention of these benefits under the circumstances alleged herein make it inequitable for Defendants to retain the benefits without payment of the value to Plaintiffs and the Class.

278. Plaintiffs and the Class are entitled to recover from Defendants all amounts wrongfully collected and improperly retained by Defendants, plus interest thereon.

279. Plaintiffs and the Class seek actual damages, injunctive and declaratory relief, attorneys' fees, costs, and any other just and proper relief available under the laws.

COUNT VIII
(Fraudulent Misrepresentation Against Defendants on Behalf of the Class)

280. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.

281. Defendants falsely represented to Plaintiffs and the Class that the Prenatal Vitamins were natural, nutritious, and nurturing of a health pregnancy.

282. Defendants intentionally, knowingly, and recklessly made these misrepresentations to induce Plaintiffs and the Class to purchase their Prenatal Vitamins.

283. Defendants knew their representations about the Prenatal Vitamins were false in that the Products contained, or may have contained, undisclosed levels of Heavy Metals that do not conform to the Products' labels, packaging, advertising, and statements. Defendants also knew their representations about the Prenatal Vitamins were false in that the Products did not contain the amount of Folic Acid promised on the Product label.

284. Defendants allowed its packaging, labels, advertisements, promotional materials, and websites to intentionally mislead consumers, such as Plaintiffs and the Class.

285. Plaintiffs and the Class did in fact rely on these misrepresentations and purchased the Prenatal Vitamins to their detriment. Given the deceptive manner in which Defendants advertised, represented, and otherwise promoted the Prenatal Vitamins, Plaintiffs' and the Class's reliance on Defendants' misrepresentations was justifiable.

286. As a direct and proximate result of Defendants' conduct, Plaintiffs and the Class have suffered actual damages in that they purchased the Prenatal Vitamins that are worth less than the price they paid and that they would not have purchased at all had they known the Products contained, or may have contained, undisclosed levels of Heavy Metals that do not conform to the Products' labels, packaging, advertising, and statements, as well as do not contain the amount of Folic Acid promised on the label.

287. Plaintiffs and the Class seek actual damages, injunctive and declaratory relief, attorneys' fees, costs, and any other just and proper relief available under the laws.

COUNT IX
(Fraud by Omission Against Defendants on Behalf of the Class)

288. Plaintiffs repeat and reallege the allegations contained above, as though fully set forth herein.

289. Defendants concealed from and failed to disclose to Plaintiffs and the Class that their Prenatal Vitamins contained, or may have contained, undisclosed levels of Heavy Metals that do not conform to the Products' labels, packaging, advertising, and statements. Defendants concealed from and failed to disclose to Plaintiffs and the Class that the Prenatal Vitamins did not contain the amount of Folic Acid promised on the Products' labels.

1 290. Defendants were under a duty to disclose to Plaintiffs and the Class the true quality,
2 characteristics, ingredients and suitability of the Prenatal Vitamins because: (1) Defendants were
3 in a superior position to know the true state of facts about their Products; (2) Defendants were in
4 a superior position to know the actual ingredients, characteristics, and suitability of the Products
5 for consumption by women who are pregnant or may become pregnant; (3) Defendants must
6 comply with legal and regulatory guidelines; and (4) Defendants knew that Plaintiffs and the
7 Class could not reasonably have been expected to learn or discover that the Products were
8 misrepresented in the packaging, labels, advertising, and websites prior to purchasing the
9 Products.

10 291. The facts concealed or not disclosed by Defendants to Plaintiffs and the Class are
11 material in that a reasonable consumer would have considered them important when deciding
12 whether to purchase the Prenatal Vitamins.

13 292. Plaintiffs and the Class justifiably relied on Defendants' omissions to their
14 detriment. The detriment is evident from the true quality, characteristics, and ingredients of the
15 Prenatal Vitamins, which is inferior when compared to how the Prenatal Vitamins are advertised
16 and represented by Defendants.

17 293. As a direct and proximate result of Defendants' conduct, Plaintiffs and the Class
18 have suffered actual damages in that they purchased the Prenatal Vitamins that are worth less than
19 the price they paid and that they would not have purchased at all had they known the Products
20 contained or risked containing Heavy Metals that do not conform to the Products' labels,
21 packaging, advertising, and statements, and had they known the Prenatal Vitamins contained, or
22 had a risk of containing, a deficient amount of Folic Acid as compared to the amount stated on
23 the Product label.

24 294. Plaintiffs and the Class seek actual damages, injunctive and declaratory relief,
25 attorney's fees, costs, and any other just and proper relief available under the laws.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf of all others similarly situated, pray for judgment against the Defendants as to each and every count, including:

A. An order declaring this action to be a proper class action, appointing Plaintiffs and their counsel to represent the Class, and requiring Defendants to bear the costs of class notice;

B. An order enjoining Defendants from selling the Prenatal Vitamins until the higher and/or unsafe levels of Heavy Metals are removed;

C. An order enjoining Defendants from selling the Prenatal Vitamins until any levels, or risk of any levels, of Heavy Metals are disclosed on the Products' labels.

D. An order enjoining Defendants from selling the Prenatal Vitamins until all Product labels reflect the accurate amount of Folic Acid contained in the Product;

E. An order enjoining Defendants from selling the Prenatal Vitamins in any manner suggesting or implying that they are natural, nutritious, and nurturing of a healthy pregnancy;

F. An order requiring Defendants to engage in a corrective advertising campaign and engage in any further necessary affirmative injunctive relief, such as recalling their existing Prenatal Vitamins;

G. An order awarding declaratory relief, and any further retrospective or prospective injunctive relief permitted by law or equity, including enjoining Defendants from continuing the unlawful practices alleged herein, and injunctive relief to remedy Defendants' past conduct;

H. An order requiring Defendants to pay restitution to restore all funds acquired by means of any act or practice declared by this Court to be an unlawful, unfair, or fraudulent business act or practice, untrue or misleading advertising, or a violation of the Unfair Competition Law, False Advertising Law, or CLRA, plus pre- and post-judgment interest thereon;

I. An order requiring Defendants to disgorge or return all monies, revenues, and profits obtained by means of any wrongful or unlawful act or practice;

J. An order requiring Defendants to pay all actual and statutory damages permitted under the counts alleged herein;

K. An order requiring Defendants to pay punitive damages on any count so allowable;

1 L. An order awarding attorneys' fees and costs to Plaintiffs and the Class; and

2 M. An order providing for all other such equitable relief as may be just and proper.

3 **JURY DEMAND**

4 Plaintiffs hereby demand a trial by jury on all issues so triable.

5 Dated: February 18, 2022

MILLER SHAH LLP

6 By: /s/ Kolin C. Tang

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**Pro Hac Vice admission to be sought*