IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

ANNA KHARAEVA and ZSAIAHNA HUFF, *individually and on behalf of all others similarly situated,* Plaintiffs, v. BAYER AG, BAYER CORPORATION, and BAYER HEALTHCARE LLC, Defendants.	Case No. CLASS ACTION COMPLAINT DEMAND FOR JURY TRIAL

CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL

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Plaintiffs, Anna Kharaeva and Zsaiahna Huff (collectively, "**Plaintiffs**"), are natural persons, residents, and citizens of the Commonwealth of Pennsylvania. Plaintiffs, individually and on behalf of all others similarly situated, bring this Class Action Complaint ("**Complaint**") against Defendants, Bayer AG, Bayer Corporation, and Bayer HealthCare LLC (collectively, "**Bayer**" or "**Defendants**"), for their negligent, reckless, and/or intentional practice of mismarketing their One A Day Prenatal Vitamin(s) ("**Products**" or "**Prenatal Vitamin(s)**")[1] sold throughout the United States. Defendants' mismarketing is twofold. First, Defendants fail to disclose the presence, or risk, of dangerous substances in their Prenatal Vitamins, including heavy metals. Second, Defendants misrepresent the quantity of ingredients in their Prenatal Vitamins, including the amount of Folic Acid. Plaintiffs seek 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 Defendants' marketing, advertising, and labeling, and restoring monies to the members of the proposed Class.

[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 One A Day® products: One A Day Prenatal Advanced Complete Multivitamin with Brain Support (60 Prenatal Multivitamin Softgels & 60 Prenatal Choline Tablets), One A Day Prenatal 1 Complete Multivitamin (60 Softgels), One A Day Prenatal 1 with DHA and Folic Acid (30 Softgels), One A Day Prenatal 1 Complete Multivitamin for Before During After Pregnancy with Folic Acid, DHA & Iron (30 Softgels), One A Day Prenatal Gummies Complete Multivitamin for Before During After Pregnancy with Folic Acid and Naturally Sourced DHA (120 Gummies), One A Day Prenatal Complete Multivitamin (60 Prenatal DHA/EPA Liquid Gels & 60 Prenatal Multivitamin Tablets), One A Day Pre-Pregnancy Couple's Pack (30 + 30 Count). 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 reserve their right to include any such products in this action.

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

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

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

3. The North America Prenatal Vitamin market was valued at an estimated 200.47 million U.S. dollars ("**USD**") in the United States in 2020, and the market is expected to increase by almost USD 100 million in the next five years, reaching a market value of USD 293.6 million, by 2025.[3]

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[2] Stephen J. Genuis, Rebecca A. Genuis, "Preconception Care: A New Standard of Care within Maternal Health Services", *BioMed Research International*, vol. 2016, Article ID 6150976, 30 pages, 2016. *Available at* https://doi.org/10.1155/2016/6150976 (last accessed January 3, 2022).

[3] North America Prenatal Vitamins Supplement Market, Market Data Forecast, *available at* https://www.marketdataforecast.com/market-reports/na-prenatal-vitamins-supplements-market (last accessed January 3, 2022) ("Vitamins Supplement Market Data Forecast").

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

5. The surge in sales of prenatal vitamins has also increased due to promotional initiatives by the market vendors, like Defendants.[6] "Prenatal vitamin supplements are gaining popularity in the market due to aggressive promotion and enhanced sales channels increasing accessibility to the consumers."[7]

6. 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]

7. 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

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[4] *Id.*

[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.*

[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 January 3, 2022).

[10] *Nutrition During Pregnancy, supra.*

Plaintiffs, read the product label to ensure its ingredients, including Folic Acid, provide the appropriate nutrition to support their prenatal health.[11]

8. Given the importance of prenatal vitamins to the mother's and baby's health, women like Plaintiffs who are pregnant or who may become pregnant trust Defendants to sell prenatal vitamins that are nutritious and nurturing of a healthy pregnancy and provide the appropriate daily amount of vitamins and minerals, 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.

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

II. Heavy Metals

10. Defendants fail to disclose the presence, or risk, of Heavy Metals in their Products.

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

12. Consumers like Plaintiffs lack the scientific knowledge necessary to determine whether the Defendants' Products do in fact contain Heavy Metals or to know or ascertain the true

[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." 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, the phrase "**Heavy Metals**" is collectively defined as Arsenic, Cadmium, Lead, and Mercury.

nature of the ingredients and quality of the Products. Reasonable consumers therefore must and do rely on Defendants to honestly report what their Products contain, especially as it pertains to the disclosure of Heavy Metals.

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

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

[13] U.S. House of Representatives, Committee on Oversight and Reform, Subcommittee on Economic and Consumer Policy, Staff Report, Baby Foods Are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury, February 4, 2021, *available at* 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 Committee Report"). *See also* U.S. House of Representatives, Committee on Oversight and 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%20Second%20Baby%20Food%20Report%209.29.21%20FINAL.pdf (last accessed January 9, 2022).

[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.*

low dose and consistent exposure to Heavy Metal toxicity to an infant during pregnancy can result in preterm delivery, stillbirth, or miscarriage.[16]

15. 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]

16. 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.

17. 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 their Prenatal Vitamins possess certain qualities and characteristics that support a mother's and developing baby's health.

18. No reasonable consumer seeing Defendants' marketing would expect Defendants' Prenatal Vitamins to contain or risk containing Heavy Metals. Furthermore, reasonable consumers,

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[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).

like Plaintiffs, would consider the mere inclusion, or risk of inclusion, of Heavy Metals a material fact when shopping for a nutritious prenatal vitamin.

19. 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 include or risk including undisclosed Heavy Metals.

20. Defendants' Prenatal Vitamins do not have a disclaimer regarding the presence of Heavy Metals that would inform consumers that the foods contain, or risk containing, Heavy Metals and/or that Heavy Metals can accumulate over time in a developing child's body to the point where negative health outcomes can occur.

III. Folic Acid

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

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

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

24. Folic Acid is critical to the health of women who are pregnant or may become pregnant. Folic Acid helps prevent babies from developing NTD including spina bifida.[19]

25. 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.

26. 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.

27. 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.

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

29. 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, Defendants' Prenatal Vitamins contained, or had a risk of containing, less Folic Acid than the amount stated on the label.

30. 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.

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

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

31. Defendants' wrongful marketing, which includes misleading, deceptive, unfair, and false marketing, and omissions, 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 their Prenatal Vitamins that are not as advertised.

32. 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

33. This Court has original jurisdiction over this action 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 Defendant; (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.

34. 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

35. This Court has personal jurisdiction over Plaintiffs, Anna Kharaeva and Zsaiahna Huff, who are residents of the Commonwealth of Pennsylvania.

36. This Court has both general and specific personal jurisdiction over the Defendants, Bayer AG, Bayer Corporation, and Bayer Healthcare LLC.

37. This Court has general personal jurisdiction over Defendants, Bayer Corporation, and Bayer Healthcare LLC, because Defendants are registered to conduct business in Pennsylvania.

38. This Court has general personal jurisdiction over Defendants, Bayer AG, Bayer Corporation, and Bayer Healthcare LLC, because the Defendants advertise, market, and sell their prenatal vitamin products in the Commonwealth of Pennsylvania, accept money from purchasers located in Pennsylvania, have engaged in systematic and continuous business activities in Pennsylvania, transacted substantial business with Pennsylvania entities and residents, and generally have sufficient minimum contacts in Pennsylvania to satisfy the Due Process Clause of the Pennsylvania Constitution and Pennsylvania's Long Arm Statute pursuant to 42 Pa. C.S § 5322.

Specific Personal Jurisdiction

39. This Court has specific personal jurisdiction over Defendants arising from Defendants' advertising, marketing, and sale of One A Day prenatal vitamin products in the Commonwealth of Pennsylvania, which at all relevant times, included or risked including dangerous substances and misrepresented the amount of Folic Acid, all of which have caused harm in Pennsylvania as a result of the specific business activities complained of herein, either directly or through Defendants' agents.

40. This Court has specific personal jurisdiction over Defendants because the advertising, marketing, and sale of One A Day prenatal vitamin products, which included or risked including dangerous substances and misrepresented the amount of Folic Acid, occurred in parts of the Commonwealth of Pennsylvania that are located in the Eastern District of Pennsylvania.

41. Venue is proper in the Eastern District of Pennsylvania under 28 U.S.C. § 1391(b)(2) because Plaintiffs, Anna Kharaeva and Zsaiahna Huff, reside in the Eastern District of Pennsylvania, and ingested the One A Day prenatal vitamin products at issue within the confines of this District.

42. Venue is proper in the Eastern District of Pennsylvania under 28 U.S.C. § 1391(b)(1)&(2) and 28 U.S.C. § 1391(d) because Defendants regularly conduct substantial business within the Eastern District of Pennsylvania.

43. Venue is also proper in the Eastern District of Pennsylvania under 28 U.S.C. § 1391(b)(2) because a substantial portion of the events or omissions giving rise to Plaintiffs' claims occurred in this District, namely, Defendants' advertisement, sale, and marketing of One A Day prenatal vitamin products, which occurred in this District and caused financial harm to members of the putative class that reside in this District.

THE PARTIES

44. Plaintiff Anna Kharaeva is, and at all times relevant hereto has been, a citizen of Philadelphia, Pennsylvania, located in the county of Philadelphia. She purchased the Prenatal Vitamins**,** specifically the One A Day Pre-Pregnancy Couple's Pack, from Amazon.com. Plaintiff Anna Kharaeva last purchased the Prenatal Vitamins from approximately June 2019 to October 2019.

45. Plaintiff Zsaiahna Huff is, and all times relevant hereto has been, a citizen of Philadelphia, Pennsylvania, located in the county of Philadelphia. She purchased the Prenatal Vitamins, specifically the One A Day Prenatal with Folic Acid, DHA, and Iron, from a Rite Aid located in Philadelphia. Plaintiff Zsaiahna Huff last purchased the Prenatal Vitamins from approximately May 2021 to September 2021.

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

47. As the result of Defendants' negligent, reckless, and/or knowingly deceptive conduct as alleged herein, Plaintiffs were injured when they paid the price premium for the Prenatal Vitamins that did not deliver what they promised. Plaintiffs paid the price premium on the assumption that the labeling of the Prenatal Vitamins was accurate, that they did not contain or risk containing undisclosed levels of Heavy Metals and were safe to ingest, and that they contained the amount of Folic Acid promised on the product label. Plaintiffs would not have paid this money had they known that the Prenatal Vitamins contained, or risked containing, levels of Heavy Metals and contained, or risked containing, a deficient amount of Folic Acid as compared to the amount stated on the Product label. Further, should Plaintiffs encounter the Prenatal Vitamins in the future, they could not rely on the truthfulness of the marketing, absent corrective changes to the

packaging, labeling, and advertising of the Prenatal Vitamins. Damages can be calculated through expert testimony at trial.

48. Defendant Bayer AG is a German multinational chemical and pharmaceutical company.

49. Defendant Bayer Corporation is an Indiana corporation and is wholly owned by Bayer AG.

50. Defendant Bayer HealthCare LLC is a Delaware limited liability company and wholly owned by Bayer Corporation. Bayer Healthcare LLC is responsible for the marketing, distribution, and sale of Bayer One A Day Prenatal Vitamins to millions of consumers throughout the United States, including the Commonwealth of Pennsylvania.

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

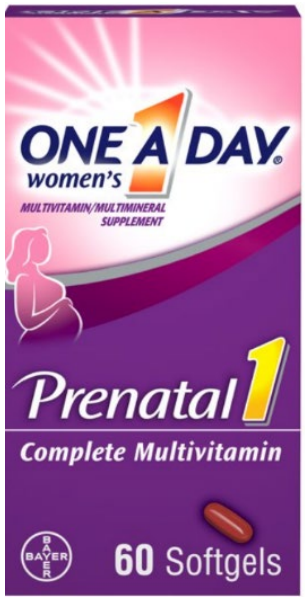
52. The marketing for the Prenatal Vitamins, relied upon by Plaintiffs, was disseminated throughout the United States, including the Commonwealth of Pennsylvania, by Defendants and their agents through advertising, packaging, and labeling that contained the misrepresentations and omissions alleged herein. Defendants' marketing for the Prenatal Vitamins was designed to encourage consumers, and reasonably misled consumers, into purchasing the Prenatal Vitamins throughout the United States, including the Commonwealth of Pennsylvania.

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

(a) One A Day Prenatal Advanced Complete Multivitamin *with Brain Support*:

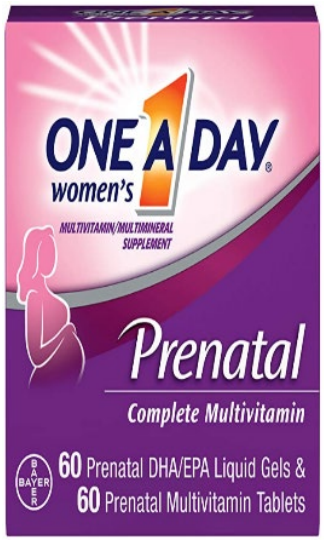


(b) One A Day Prenatal 1 Complete Multivitamin Tablets (60 count):

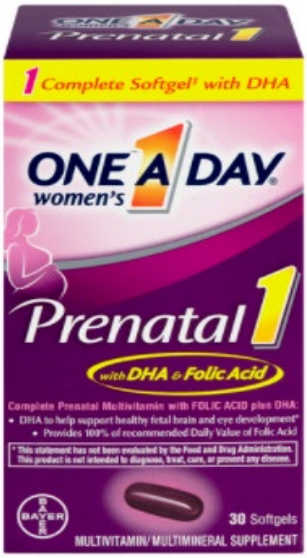


[20] As stated *supra*, discovery may reveal additional products that also contain levels of Heavy Metals and reflect an inaccurate amount of Folic Acid than the amount depicted on the product label. Plaintiffs reserve the right to include any such products in this action. Plaintiffs reserve the right to amend and/or supplement the labels included in the Complaint in accordance with applicable Federal and Pennsylvania law.

(c) One A Day Prenatal DHA/EPA Liquid Gels (60 count):



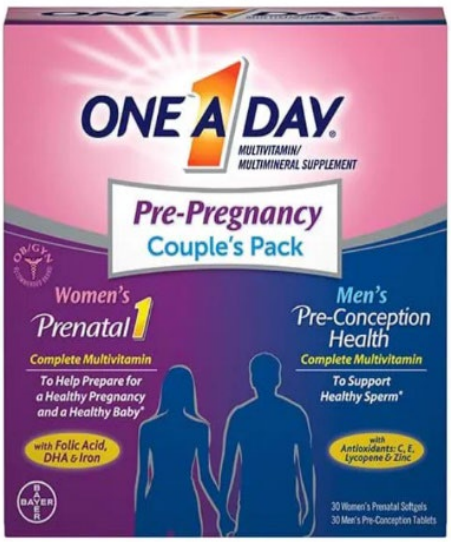
(d) One A Day Prenatal DHA and Folic Acid (30 count):



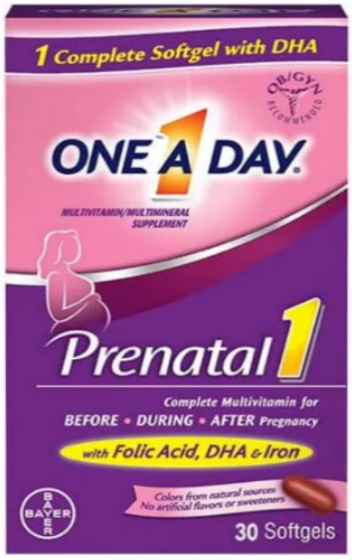
(e) One A Day Prenatal Gummies (120 count):



(f) One A Day Prenatal Couple's Pack (30 + 30 count)



(g) One A Day Prenatal with Folic Acid, DHA, and Iron (30 count)



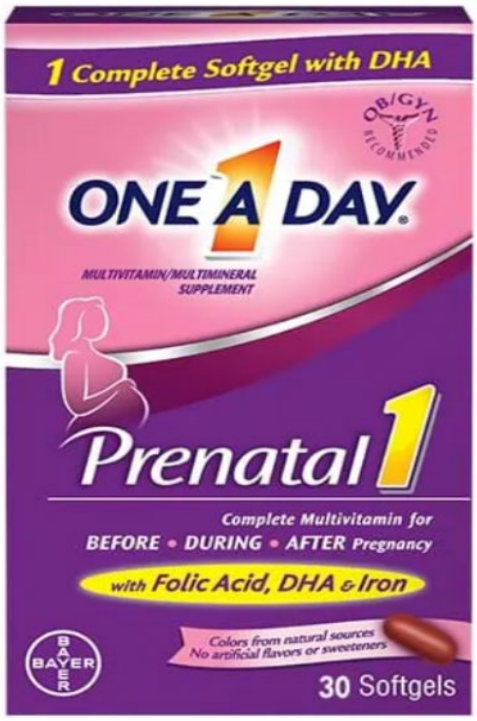
FACTUAL ALLEGATIONS

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

54. Defendants' package, label, market, advertise, formulate, manufacture, distribute, and sell their products, including their Prenatal Vitamins throughout Pennsylvania 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.

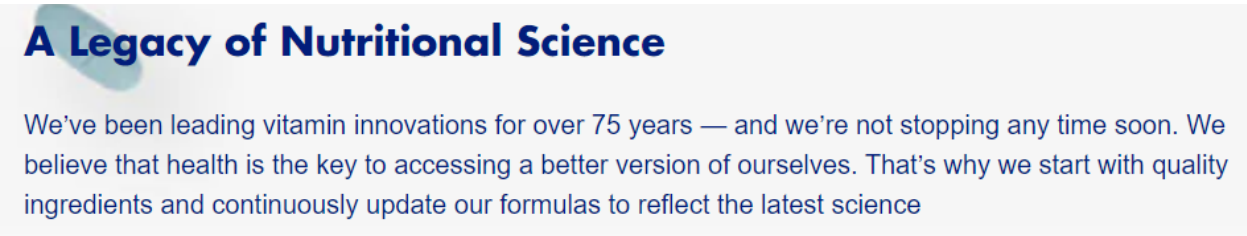
55. Defendants' Prenatal Vitamins are advertised with the "One A Day" brand to reflect and imply that consumers would receive the appropriate daily amount of vitamins and minerals by taking the Products once a day - or, in the case of the One A Day Prenatal Gummies - twice per day.

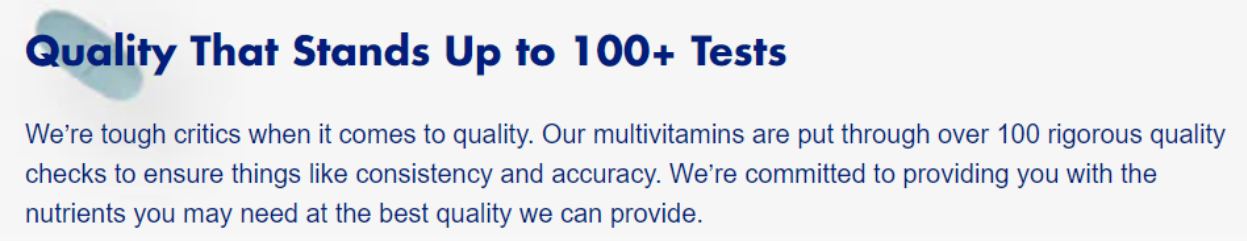
56. Defendants' market their Prenatal Vitamin as "complete" with packaging that includes images of a pregnant woman with the directions to take "BEFORE DURING AFTER Pregnancy."



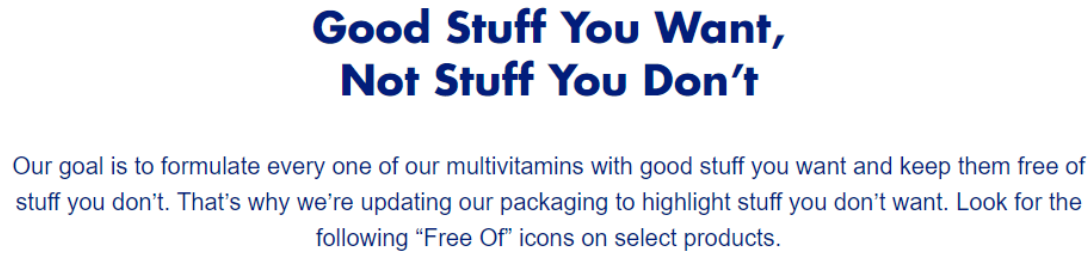


57. On their website, Defendants' promise "A Legacy of Nutritional Science" and "Quality That Stands Up to 100+ Tests."[21]





58. Defendants also declare "Good Stuff You Want, Not Stuff You Don't" on their website, and state they are "updating their packaging to highlight stuff you don't want."[22]



59. With their marketed once daily Products, "legacy" and quality, and the "good stuff […] not stuff you don't," Defendants clearly recognize the importance of their Prenatal Vitamins

[21] https://www.oneaday.com/why-choose-one-a-day-vitamins (last accessed January 3, 2022).

[22] https://www.oneaday.com/why-choose-one-a-day-vitamins (last accessed January 3, 2022).

to the healthy development of a baby in-utero, including a woman's preparation to foster such development.

II. DEFENDANTS' SOURCING, FORMULATION, AND TESTING PROCEDURES PROVIDED THEM WITH EXCLUSIVE KNOWLEDGE OF THE PHYSICAL AND CHEMICAL MAKE-UP OF THEIR PRENATAL VITAMINS

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

61. Defendants' website describes their leadership in vitamin innovations, quality checks to ensure consistent and accurate vitamins, and expertly-designed formulas.[23] For example, Defendants "research important dietary nutrients in developing our unique formulas."[24]

62. On their website, Defendants state "Our goal is to formulate every one of our multivitamins with good stuff you want and keep them free of stuff you don't."[25]

63. Defendants' website describes their product testing, stating their Products are "put through over 100 rigorous quality checks to ensure things like consistency and accuracy."[26] Defendants are "committed to providing […] nutrients […] at the best quality we can provide."[27]

64. With their marketed sourcing, formulation, and testing procedures, Defendants clearly recognize the importance of quality ingredients in their Prenatal Vitamins, as well as accurate representation of the amount of those ingredients on the Product label, to the healthy development of a baby in-utero, including a woman's preparation to foster such development.

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[23] https://www.oneaday.com/why-choose-one-a-day-vitamins (last accessed January 3, 2022)

[24] *Id*.

[25] *Id*.

[26] *Id.*

[27] *Id*.

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

A. Defendants Falsely Marketed their Prenatal Vitamins by Omitting the Inclusion or Risk of Heavy Metals

65. Defendants promote their Prenatal Vitamins as "complete" Products. *See Supra* ¶ 44. Defendants label their Products as a "Complete Multivitamin To Help Prepare For a Healthy Pregnancy and a Healthy Baby." *Id*. at ¶ 44(f).

66. Defendants label their Products as formulated to "Support Your Pregnancy from Start to Finish."[28]



[28] https://www.oneaday.com/vitamins/prenatal-pregnancy-vitamins (last accessed January 3, 2022)

67. Defendants promote their Prenatal Vitamins as formulated to "support fetal brain and eye development" and to "support healthy sperm."[29]

68. Based on Defendants' decision to advertise, label, and market their Prenatal Vitamins as nutritious and nurturing of a healthy pregnancy, and with the appropriate daily amount of vitamins and minerals consistent with the One A Day 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 had a risk of including, nondisclosed levels of Heavy Metals, especially considering Defendants' statements on their website and labels and packaging.

69. Defendants' marketing of the Products failed to disclose they contained or were at risk of containing any level of Heavy Metals.

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

71. As a result of Defendants' omissions, a reasonable consumer would have no reason to suspect the presence, or risk, of undisclosed levels of Heavy Metals in the Products, a reasonable consumer would have no way of determining the level of Heavy Metals the Products contained, 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 their Prenatal Vitamins, Defendants' Marketing and Omissions are Misleading

72. At all times during the Class Period, Defendants knew or should have known the Prenatal Vitamins contained, or risked containing, Heavy Metals. Defendants thoroughly test their Products, subjecting the Products to "over 100 rigorous quality checks to ensure things like

[29] https://www.oneaday.com/vitamins/prenatal-pregnancy-vitamins/his-hers-pregnancy-vitamin (last accessed January 3, 2022)

consistency and accuracy."[30] Additionally, as a result of a publicly released 2008 Food and Drug Administration ("**FDA**") survey on lead in women's and children's vitamins ("**2008 FDA Survey**"), Defendants knew or should have known their Prenatal Vitamins may have been contaminated with Lead as Lead was found in several of their children's vitamins and one of their women's vitamin. [31]

73. Plaintiffs, through counsel, submitted a Freedom of Information Act ("**FOIA**") request to the FDA on March 10, 2021 asking for any tests results or any records related to the levels of Folic Acid or Heavy Metals in One A Day prenatal vitamins. On July 28, 2021, the FDA responded that it was unable to locate any records in response to the request.

74. Defendants' Prenatal Vitamins contained or had a risk of containing Heavy Metals. Defendants were aware of this risk due to their proclaimed sourcing, formulation, and testing procedures, and Defendants failed to disclose it to Plaintiffs and the Class.

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

76. Heavy Metal exposure can lead to catastrophic health consequences in a developing baby. The fetal development period from conception until birth is a phase of life that carries particular vulnerability to toxic exposure, including Heavy Metals, as developing babies have an

[30] https://www.oneaday.com/why-choose-one-a-day-vitamins (last accessed January 3, 2022).

[31] FDA, "Survey Data on Lead in Women's and Children's Vitamins," August 2008 (content current as of January 12, 2018), *available at* 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").

immature detoxification capability.[32] Due to this vulnerable state, during this critical period, a child may amass higher levels of Heavy Metals and thus experience higher levels of toxic exposure than their mothers.[33] This exposure may lead to adverse consequences in pregnancy and to the in-utero baby, including premature delivery, and the baby having a decreased birth weight, as well as smaller head and chest circumference, and a multitude of developmental and long-term health problems.[34] Prenatal exposure to Heavy Metals also negatively affects a child's neurodevelopment and may contribute to schizophrenia and dementia in adulthood.[35]

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

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

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

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

[33] *Id.*

[34] *Id.*

[35] *Id.*

Heavy Metal Ingredient: Arsenic

80. Defendants' Prenatal Vitamins contain, or risk containing, Arsenic, which can cause cancer in humans, as well as diabetes and atherosclerosis, and potentially cardiovascular disease when ingested chronically.[36] Chronic exposure to Arsenic has also been associated with dermatological lesions and malignancies.[37]

81. 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]

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[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.*

82. 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 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]

83. 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]

84. 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

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

[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.*

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]

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

Heavy Metal Ingredient: Cadmium

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

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

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[47] *Id.*

[48] *Id.*

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

[50] Genchi, G., Sinicropi, M.S., Lauria, G., Carocci, A., & Catalano, A., "The Effects of Cadmium Toxicity," International Journal of Environmental Research and Public Health, Review, Published 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).

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

[52] *Id.*

[53] *Id.*

88. Cadmium may seriously affect the morbidity and mortality of newborns in the first four weeks of their lives with far-reaching health consequences.[54] Scientists have reported a "tripling of risk for learning disabilities and special education among children with higher cadmium exposures, at levels common among U.S. children[.]"[55] Cadmium is also associated with decreases in IQ[56] and the development of ADHD.[57] Compounding the concern is that Cadmium has a prolonged half-life as it sequesters in body tissue.[58]

89. 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. Regardless, Cadmium, like Lead, "displays a troubling ability to cause harm at low levels of exposure."[59]

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[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 elements. *Toxicology international*, *20*(1), 108–112. *Available at* https://uk01.l.antigena.com/l/iZXjsQrNT77vHESOR90O688rqXKvVrIr5aILyBuFJjcUetYnfcPk-_ODeeCGEPdUpnHh_y9f2v8X~UwZvPuxZaY~OLuWrFI2odaiMcsVAACVxs_a1FMY1yM7DYVXZZLVV7s7pWn~RMZNz_mFashQLhnxB6EOghKJSew~7T (last accessed January 3, 2022).

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

[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] *Healthy Babies Bright Futures Report* at 14*, supra.*

Heavy Metal Ingredient: Lead

90. Defendants' Prenatal Vitamins contain, or risk containing, Lead, which is a probable carcinogen[60] and developmental toxin known to cause health problems to children in-utero.[61] 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.[62]

91. Prenatal Lead exposure can seriously harm a baby's neurodevelopment, and is associated with a range of negative health outcomes such as schizophrenia and dementia, decreased cognitive performance, and reduced postnatal growth.[63] Prenatal exposures to the highest and lowest levels of Lead were linked to a heightened risk of autism spectrum diagnosis in children.[64] Additionally, studies have established a link between Lead exposure and ADHD.[65]

[60] 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).

[61] *Heavy metal contamination of prenatal vitamins, supra.*

[62] 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").

[63] *Heavy metal contamination of prenatal vitamins, supra.*

[64] "ADHD and Autism Associated with In-Utero Heavy Metals and Essential Minerals," Neuroscience News, April 9, 2021, *available at* https://neurosciencenews.com/asd-adhd-heavy-metals-18207/ (last accessed January 3, 2022).

[65] *Congressional Committee Report, supra*.

92. Prenatal Lead exposure is also linked to an increased risk of a preterm birth and reduced postnatal development.[66] Maternal Lead exposure may also contribute to the baby developing certain types of congenital heart disease.[67]

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

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

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

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

94. Although no federal standard for Lead in prenatal vitamins has been established,[68] there is no known "safe" level of Lead exposure.[69] 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."[70]

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[66] *Heavy metal contamination of prenatal vitamins, supra.*

[67] *Id.*

[68] *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.

[69] *Heavy metal contamination of prenatal vitamins, supra.*

[70] *Id.*

Heavy Metal Ingredient: Mercury

95. 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.[71]

96. Developing fetuses are exceptionally vulnerable to Mercury exposure.[72] In a pregnant woman, Mercury can easily pass through the placenta and accumulate in the fetus as the fetus cannot excrete Mercury.[73] This lack of self-defense leaves a baby in-utero exposed to Mercury that may result in decreased placental and fetal development,[74] and permanent damage to the nervous system.[75]

97. Although there is no maximum contaminant level for Mercury in prenatal vitamins, the EPA has set a maximum contaminant level for Mercury in drinking water at 2 ppb.[76] However, "there is no known safe level" of exposure to Mercury as it is a "highly toxic element."[77]

98. Exposure to any one of the four Heavy Metals – Arsenic, Cadmium, Lead, and Mercury – poses significant detriments to children, especially during the gestational period.[78] Of

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[71] 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").

[72] *Id.*

[73] *Id.*

[74] 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").

[75] *Mercury Exposure and Children's Health, supra.*

[76] *Congressional Committee Report, supra*.

[77] *Mercury Exposure and Children's Health, supra.*

[78] *Heavy metal contamination of prenatal vitamins, supra.*

additional concern to developing babies are the health risks due to exposure to multiple Heavy Metals simultaneously, as "co-exposures can have interactive adverse effects."[79]

99. Understanding the detriment that exposure to Heavy Metals can create, the FDA has acknowledged that "exposure to [these four heavy] metals are likely to have the most significant impact on public health" and has prioritized them in connection with its Toxic Elements Working Group, which is aimed toward reducing human exposure to contaminants in dietary supplements, food and cosmetics.[80]

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

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

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

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

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[79] Morello-Frosch R, Cushing LJ, Jesdale BM, Schwartz JM, Guo W, Guo T, Wang M, Harwani S, Petropoulou SE, Duong W, Park JS, Petreas M, Gajek R, Alvaran J, She J, Dobraca D, Das R, Woodruff TJ. Environmental Chemicals in an Urban Population of Pregnant Women and Their 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).

[80] FDA, "Metals and Your Food," Current as of April 8, 2021, *available at* https://www.fda.gov/food/chemicals-metals-pesticides-food/metals-and-your-food (last accessed January 3, 2022).

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

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

106. Defendants' marketing was misleading due to their failure to properly and sufficiently monitor for Heavy Metals and for failure to disclose the risk or presence of Heavy Metals in the Prenatal Vitamins.

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

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

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

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

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

112. 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.

113. Defendants' above-referenced statements, representations, 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.

114. 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 and/or concealment of the presence or risk of Heavy Metals in the Prenatal Vitamins coupled with the misrepresentations alleged herein that were intended to and did, in fact, cause consumers like Plaintiffs and the members of the Class to purchase Products they would not have if the true quality and ingredients were disclosed.

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

115. Defendants' marketing wrongfully represents to consumers that their Prenatal Vitamins have certain superior quality and characteristics that they do not actually possess.

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

117. Plaintiffs' counsel had Defendants' Prenatal Vitamins tested and that testing confirmed that the Products contain, or risk containing, undisclosed Heavy Metals.

118. The highest levels of Arsenic were 1035.15 ppb in One A Day Prenatal Multivitamin Tablets (60 count).

119. The highest levels of Cadmium were 372.43 ppb in One A Day Prenatal Multivitamin Tablets (60 count), and 253.00 ppb in One A Day Prenatal 1.

120. The highest levels of Lead were 243.56 ppb in One A Day Prenatal Multivitamin Tablets (60 count) and 136.00 ppb in One A Day Prenatal 1.

121. The highest levels of Mercury were 0.92 ppb in One A Day Prenatal Gummies (120 count).

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

123. Defendants' marketing wrongfully fails to disclose to consumers the presence or risk of Heavy Metals in their Prenatal Vitamins.

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

125. Reasonable consumers must and do rely on Defendants to honestly report what their Prenatal Vitamins contain.

126. In light of Defendants' marketing, Defendants knew or should have known the Prenatal Vitamins contained or risked containing Heavy Metals.

127. Defendants intended for consumers to rely on their marketing, and reasonable consumers did in fact so rely.

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

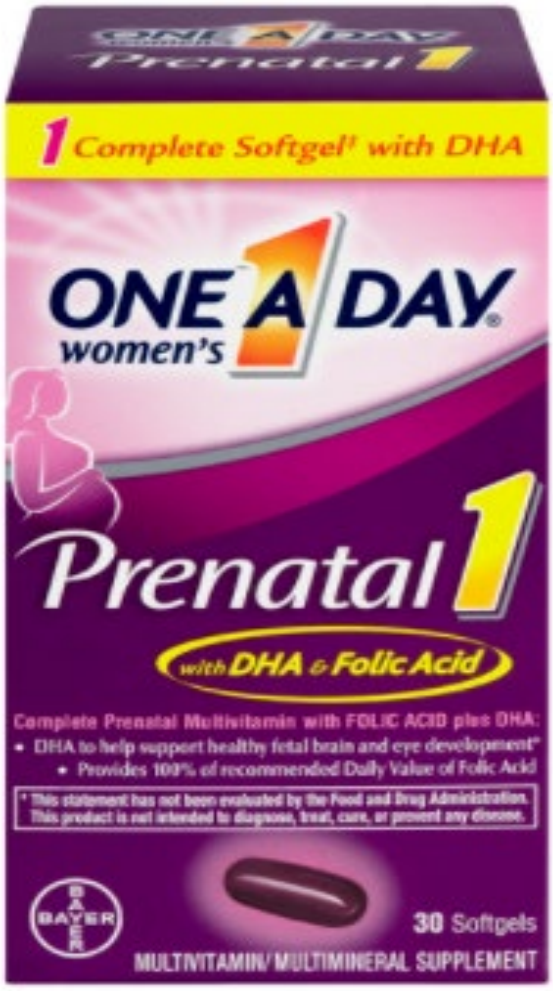
129. Pursuant to the foregoing, Defendants' marketing is deceptive, misleading, unfair, and false to Plaintiffs and other consumers, including under the consumer protection laws of Pennsylvania, as described more fully herein.

130. Defendants acted negligently, recklessly, unfairly, and/or intentionally with their deceptive, misleading, unfair, and false marketing, and omissions.

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

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

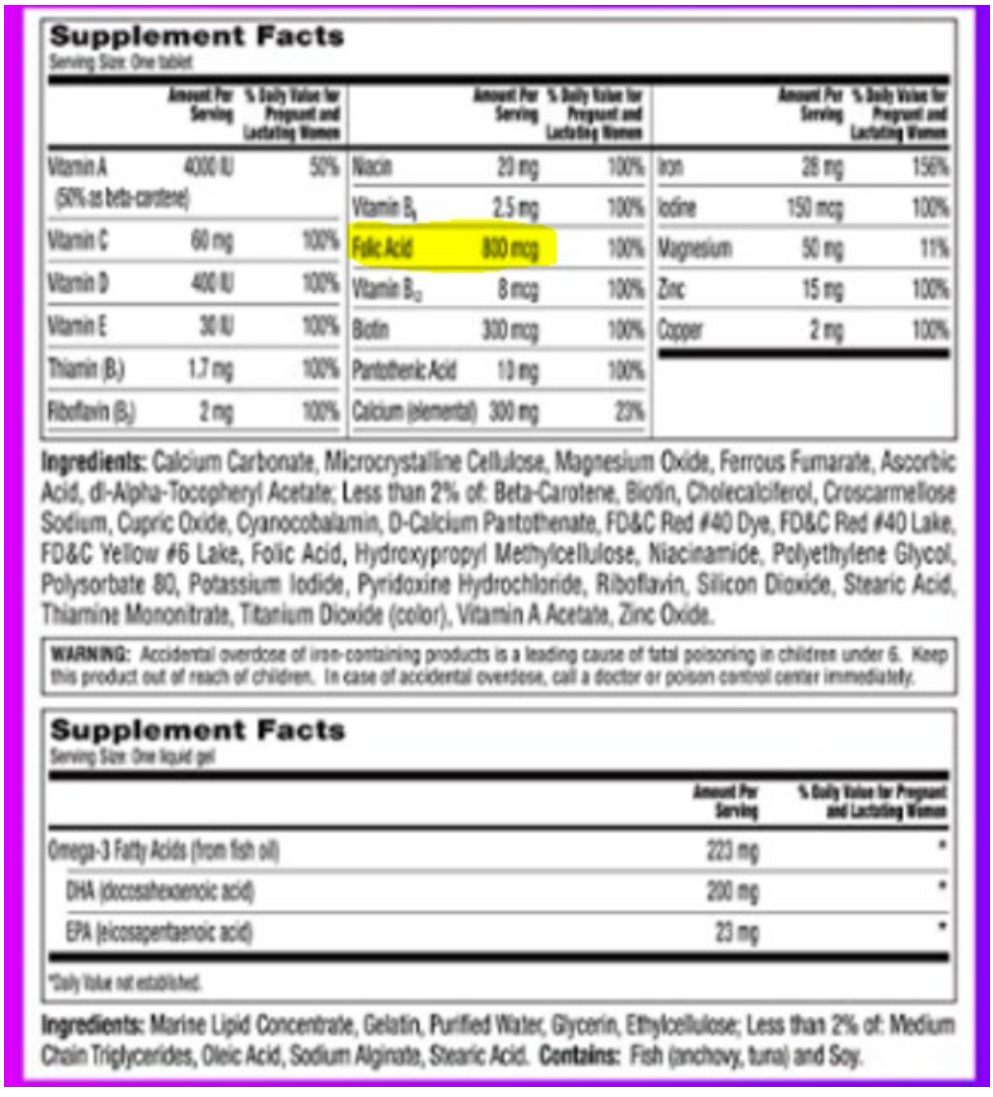
131. Defendants market their Vitamins as "[p]rovid[ing] 100% of recommended Daily Value of Folic Acid."



132. Defendants promote that their Products "support fetal brain and spinal cord development with Folic Acid."[81]

133. Each of Defendants' Products states on the "Supplement Facts" label that they contain 500 or 800 micrograms ("**mcg**") of Folic Acid.

(a) One A Day Prenatal Complete Multivitamin (60 Prenatal DHA/EPA Liquid Gels & 60 Prenatal Multivitamin Tablets)



Supplement Facts

Serving Size: One tablet

	Amount Per Serving	% Daily Value for Pregnant and Lactating Women
Vitamin A (50% as beta-carotene)	4000 IU	50%
Vitamin C	60 mg	100%
Vitamin D	400 IU	100%
Vitamin E	30 IU	100%
Thiamin (B_1)	1.7 mg	100%
Riboflavin (B_2)	2 mg	100%
Niacin	20 mg	100%
Vitamin B_6	2.5 mg	100%
Folic Acid	800 mcg	100%
Vitamin B_{12}	8 mcg	100%
Biotin	300 mcg	100%
Pantothenic Acid	10 mg	100%
Calcium (elemental)	300 mg	23%
Iron	28 mg	156%
Iodine	150 mcg	100%
Magnesium	50 mg	11%
Zinc	15 mg	100%
Copper	2 mg	100%

Ingredients: Calcium Carbonate, Microcrystalline Cellulose, Magnesium Oxide, Ferrous Fumarate, Ascorbic Acid, dl-Alpha-Tocopheryl Acetate; Less than 2% of: Beta-Carotene, Biotin, Cholecalciferol, Croscarmellose Sodium, Cupric Oxide, Cyanocobalamin, D-Calcium Pantothenate, FD&C Red #40 Dye, FD&C Red #40 Lake, FD&C Yellow #6 Lake, Folic Acid, Hydroxypropyl Methylcellulose, Niacinamide, Polyethylene Glycol, Polysorbate 80, Potassium Iodide, Pyridoxine Hydrochloride, Riboflavin, Silicon Dioxide, Stearic Acid, Thiamine Mononitrate, Titanium Dioxide (color), Vitamin A Acetate, Zinc Oxide.

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

Supplement Facts

Serving Size: One liquid gel

	Amount Per Serving	% Daily Value for Pregnant and Lactating Women
Omega-3 Fatty Acids (from fish oil)	223 mg	*
DHA (docosahexaenoic acid)	200 mg	*
EPA (eicosapentaenoic acid)	23 mg	*

*Daily Value not established.

Ingredients: Marine Lipid Concentrate, Gelatin, Purified Water, Glycerin, Ethylcellulose; Less than 2% of: Medium Chain Triglycerides, Oleic Acid, Sodium Alginate, Stearic Acid. **Contains:** Fish (anchovy, tuna) and Soy.

81 https://www.oneaday.com/vitamins/prenatal-pregnancy-vitamins/his-hers-pregnancy-vitamin (last accessed January 3, 2022)

(b) One A Day Prenatal Gummies with Folic Acid and Naturally Sourced DHA (120 Gummies)



Directions: Adults: **Fully chew** two gummies daily.

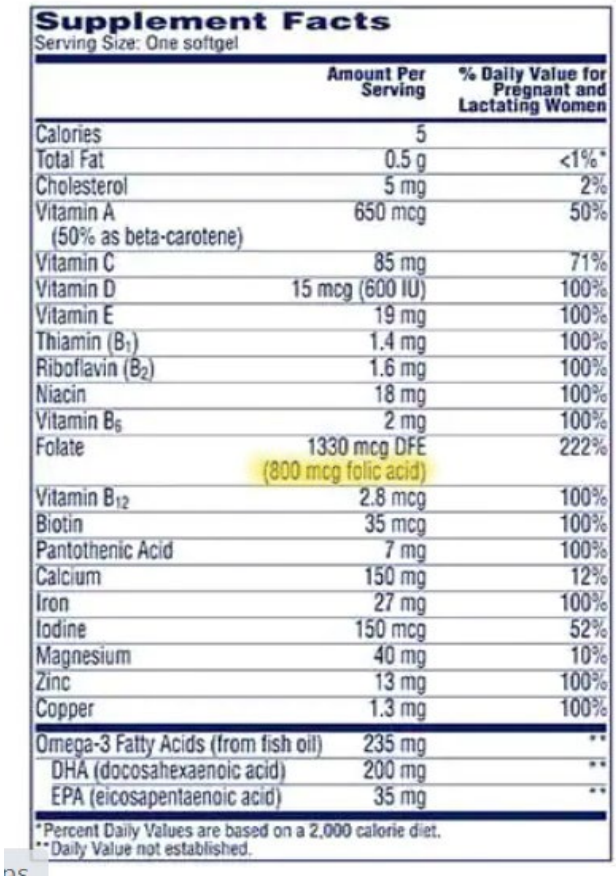
Supplement Facts

Serving Size: Two gummies
Servings Per Container: 60

	Amount Per Serving	% Daily Value for Pregnant and Lactating Women
Calories	15	
Total Carbohydrate	3 g	1%*
Total Sugars	2 g	**
Includes 2g Added Sugars		4%*
Vitamin A	650 mcg	50%
Vitamin C	60 mg	50%
Vitamin D	30 mcg (1200 IU)	200%
Vitamin E	12.7 mg	67%
Niacin	18 mg	100%
Vitamin B_6	2 mg	100%
Folate	1330 mcg DFE (800 mcg folic acid)	222%
Vitamin B_{12}	2.8 mcg	100%
Biotin	35 mcg	100%
Pantothenic Acid	7 mg	100%
Iron	0 mg	0%
Iodine	150 mcg	52%
Zinc	2.6 mg	20%
Sodium	10 mg	<1%
Omega-3 DHA (docosahexaenoic acid)	50 mg	**

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

(c) One A Day Prenatal with DHA, Folic Acid & Iron (30 Softgels)



Supplement Facts

Serving Size: One softgel

	Amount Per Serving	% Daily Value for Pregnant and Lactating Women
Calories	5	
Total Fat	0.5 g	<1%*
Cholesterol	5 mg	2%
Vitamin A (50% as beta-carotene)	650 mcg	50%
Vitamin C	85 mg	71%
Vitamin D	15 mcg (600 IU)	100%
Vitamin E	19 mg	100%
Thiamin (B_1)	1.4 mg	100%
Riboflavin (B_2)	1.6 mg	100%
Niacin	18 mg	100%
Vitamin B_6	2 mg	100%
Folate	1330 mcg DFE (800 mcg folic acid)	222%
Vitamin B_{12}	2.8 mcg	100%
Biotin	35 mcg	100%
Pantothenic Acid	7 mg	100%
Calcium	150 mg	12%
Iron	27 mg	100%
Iodine	150 mcg	52%
Magnesium	40 mg	10%
Zinc	13 mg	100%
Copper	1.3 mg	100%
Omega-3 Fatty Acids (from fish oil)	235 mg	**
DHA (docosahexaenoic acid)	200 mg	**
EPA (eicosapentaenoic acid)	35 mg	**

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

(d) One A Day Prenatal Advanced Complete Multivitamin with Brain Support (60 Prenatal Multivitamin Softgels & 60 Prenatal Choline Tablets)



Directions: Adults, take one softgel and one tablet daily with food.

Supplement Facts

Serving Size: One softgel

	Amount Per Serving	% Daily Value for Pregnant and Lactating Women
Calories	5	
Total Fat	0.5 g	<1%*
Cholesterol	5 mg	2%
Vitamin A (50% as beta-carotene)	650 mcg	50%
Vitamin C	85 mg	71%
Vitamin D	15 mcg (600 IU)	100%
Vitamin E	19 mg	100%
Thiamin (B_1)	1.4 mg	100%
Riboflavin (B_2)	1.6 mg	100%
Niacin	18 mg	100%
Vitamin B_6	2 mg	100%
Folate	1330 mcg DFE (800 mcg folic acid)	222%
Vitamin B_{12}	2.8 mcg	100%
Biotin	35 mcg	100%
Pantothenic Acid	7 mg	100%
Calcium	150 mg	12%
Iron	27 mg	100%
Iodine	150 mcg	52%
Magnesium	40 mg	10%
Zinc	13 mg	100%
Copper	1.3 mg	100%
Omega-3 Fatty Acids (from fish oil)	235 mg	**
DHA (docosahexaenoic acid)	200 mg	**
EPA (eicosapentaenoic acid)	35 mg	**

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

Ingredients: Omega-3 Fish Oil, Calcium Carbonate, Gelatin, Glycerin, Calcium Ascorbate, Yellow Beeswax, Magnesium Oxide; Less than 2% of: Beta-Carotene, Biotin, Carbonyl Iron, Color (Annatto Extract [seed]), Cupric Oxide, Cyanocobalamin, d-Alpha-Tocopherol, D-Calcium Pantothenate, Folic Acid, Niacinamide, Potassium Iodide, Purified Water, Pyridoxine Hydrochloride, Retinyl Palmitate, Riboflavin, Soy Lecithin, Thiamine Mononitrate, Vitamin D_3 (Cholecalciferol), Zinc Oxide.

Contains: Fish (anchovy, sardine, tuna) and Soy.

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

Supplement Facts

Serving Size: One tablet

	Amount Per Serving	% Daily Value for Pregnant and Lactating Women
Choline	110 mg	20%

Ingredients: Choline Bitartrate, Dicalcium Phosphate, Microcrystalline Cellulose, Food Starch-Modified, Acacia; Less than 2% of: Carnauba Wax, Hydroxypropyl Methylcellulose, Inulin, Magnesium Stearate, Medium Chain Triglycerides.

SEE LEFT SIDE PANEL FOR ADDITIONAL WARNINGS

(e) One A Day Pre-Pregnancy Couple's Pack Women's Prenatal 1 Complete Multivitamin and Men's Pre-Conception Health Complete Multivitamin (30 Women's Prenatal Softgels + 30 Men's Pre-Conception Tablets)

FOR HER:

Supplement Facts
Serving Size: One softgel

	Amount Per Serving	% Daily Value for Pregnant and Lactating Women
Calories	5	
Total Fat	0.5 g	<1%*
Cholesterol	5 mg	2%
Vitamin A (50% as beta-carotene)	650 mcg	50%
Vitamin C	85 mg	71%
Vitamin D	15 mcg (600 IU)	100%
Vitamin E	19 mg	100%
Thiamin (B_1)	1.4 mg	100%
Riboflavin (B_2)	1.6 mg	100%
Niacin	18 mg	100%
Vitamin B_6	2 mg	100%
Folate (800 mcg folic acid)	1330 mcg DFE	222%
Vitamin B_{12}	2.8 mcg	100%
Biotin	35 mcg	100%
Pantothenic Acid	7 mg	100%
Calcium	150 mg	12%
Iron	27 mg	100%
Iodine	150 mcg	52%
Magnesium	40 mg	10%
Zinc	13 mg	100%
Copper	1.3 mg	100%
Omega-3 Fatty Acids (from fish oil)	235 mg	**
DHA (docosahexaenoic acid)	200 mg	**
EPA (eicosapentaenoic acid)	35 mg	**

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

FOR HIM:

Supplement Facts
Serving Size: One tablet

	Amount Per Serving	% Daily Value
Vitamin A (11% as beta-carotene)	810 mcg	90%
Vitamin C	100 mg	111%
Vitamin D	20 mcg (800 IU)	100%
Vitamin E	45 mg	300%
Thiamin (B_1)	1.2 mg	100%
Riboflavin (B_2)	1.3 mg	100%
Niacin	16 mg	100%
Vitamin B_6	1.3 mg	76%
Folate (500 mcg folic acid)	830 mcg DFE	208%
Vitamin B_{12}	2.4 mcg	100%
Biotin	30 mcg	100%
Pantothenic Acid	5 mg	100%
Calcium	260 mg	20%
Iodine	150 mcg	100%
Magnesium	140 mg	33%
Zinc	15 mg	136%
Selenium	55 mcg	100%
Copper	0.9 mg	100%
Manganese	2.3 mg	100%
Chromium	35 mcg	100%
Lycopene	6 mg	*

*Daily Value not established.

(f) One A Day Prenatal Complete Multivitamin (60 Softgels)

Supplement Facts

Serving Size: One softgel

	Amount Per Serving	% Daily Value for Pregnant and Lactating Women
Calories	5	
Calories From Fat	5	
Total Fat	0.5 g	*
Polyunsaturated Fat	0.5 g	*
Cholesterol	25 mg	*
Total Carbohydrate	0 g	*
Sugars	0 g	*
Vitamin A (50% as beta-carotene)	4000 IU	50%
Vitamin C	60 mg	100%
Vitamin D	400 IU	100%
Vitamin E	30 IU	100%
Thiamin (B_1)	1.7 mg	100%
Riboflavin (B_2)	2 mg	100%
Niacin	20 mg	100%
Vitamin B_6	2.5 mg	100%
Folic Acid	800 mcg	100%
Vitamin B_{12}	8 mcg	100%
Biotin	300 mcg	100%
Pantothenic Acid	10 mg	100%
Calcium	200 mg	15%
Iron	28 mg	156%
Iodine	150 mcg	100%
Magnesium	50 mg	11%
Zinc	15 mg	100%
Copper	2 mg	100%
Omega-3 Fatty Acids (from fish oil)	235 mg	*
DHA (docosahexaenoic acid)	200 mg	*
EPA (eicosapentaenoic acid)	35 mg	*

*Daily Value not established.

Ingredients: Calcium Carbonate, Omega-3 Fish Oil, Gelatin, Glycerin, Magnesium Oxide, Yellow Beeswax, Ascorbic Acid, d-Alpha Tocopherol; Less than 2% of: Beta-Carotene, Biotin, Carbonyl Iron, Color (Annatto Extract [seed]), Cupric Oxide, Cyanocobalamin, D-Calcium Pantothenate, Folic Acid, Niacinamide, Potassium Iodide, Purified Water, Pyridoxine Hydrochloride, Retinyl Palmitate, Riboflavin, Soy Lecithin, Thiamine Mononitrate, Vitamin D_3 (Cholecalciferol), Zinc Oxide.

Contains: Fish (anchovy, jack mackerel, sardine, tuna) and Soy.

134. Defendants' marketing of their Products' Folic Acid, along with Defendants falsely stating as "fact" that the Prenatal Vitamins contain 500 or 800 mcg in a daily serving, demonstrates their recognition of the importance of Folic Acid in the development of a baby in-utero.

135. Based on Defendants' decision to market their Prenatal Vitamins as containing 500 or 800 mcg of Folic Acid in a daily serving, 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.

136. 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 promised on the Products' labels, while also promoting the Products' inclusion of Folic Acid to "support fetal brain and spinal cord development[.]"

137. 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 these products.

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

138. 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 containing "100% of recommended Daily Value of Folic Acid" and as a "complete multivitamin to help prepare for a healthy pregnancy and a healthy baby."

139. Defendants assert that they conduct thorough testing of their Products, and are subject to legal and regulatory compliance regarding their manufacturing practices.

140. Defendants knew or should have known their Prenatal Vitamins contained or had a risk of containing less Folic Acid than promised on the Products' labels due to Defendants' exclusive knowledge of the physical and chemical make-up of the Prenatal Vitamins, their requirement to comply with the law and regulation, and the 2008 FDA Survey that identified several of Defendant's children's vitamins and one of their women's vitamins as being contaminated with Lead.

141. 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.

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

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

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

145. The labels for Defendants' Prenatal Vitamins represent that the products contain 500 or 800 mcg Folic Acid. But Defendants' Products contain a different amount of Folic Acid than what is represented on their labels.

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

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

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

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

150. 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.

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

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

153. 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

154. 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.[82] Studies have shown that proper allowances of Folic Acid can help prevent miscarriage, birth defects, NTDs such as spina bifida (which affects the spine) and anencephaly (which affects the brain), as well as skull malformation.[83] Therefore, Folic Acid consumption is critical for prenatal health.

155. 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.[84] Moreover, the human body absorbs more Folic Acid from fortified foods and supplements than from Folate naturally found in foods.[85] Therefore, Folic Acid is used in supplements to help humans meet their nutritional needs.[86] 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.

156. Underscoring the importance of Folate to the nutrition of women of a childbearing age to a healthy pregnancy, and given the difficulty for most women to get the daily recommended amount of Folate through diet alone,[87] in January 1998, the FDA required food manufacturers to

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[82] 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").

[83] *Folate Fact Sheet for Health Professionals, supra*.

[84] 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").

[85] 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).

[86] *HHS Folic Acid, supra.*

[87] *CDC Folic Acid, supra.*

add Folic Acid to commonly consumed foods, including breads, cereals, rice, pasta, and other grains, to decrease the risk of NTDs.[88]

157. Three thousand pregnancies every year in the U.S. are affected by NTDs.[89] 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."[90] However, with Folic Acid fortification, NTD prevalence decreased by thirty-six percent in the U.S.[91]

158. Therefore, Folic Acid is vital for women to consume prior to and during pregnancy to support prenatal health.[92] The less Folic Acid a woman who is pregnant or may become pregnant consumes, the more likely the baby will develop NTDs.[93]

159. Defendants' labels for their Prenatal Vitamins state that the Products contain 800 **mcg** of Folic Acid.

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[88] 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).

[89] 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).

[90] *Id.*

[91] *Id.*

[92] *CDC Folic Acid, supra.*

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

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

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

162. Defendants knew or should have known the amount of Folic Acid contained in their Prenatal Vitamins was inconsistent with their marketing. The Products contained an amount of Folic Acid inconsistent with the amount Defendants represented on the labels.

163. Defendants knew or should have known that consumers expected them to ensure the amount of Folic Acid in their Products was 500 or 800 mcg per daily serving to comply with their marketing.

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

165. Defendants' above-referenced statements and representations are false, misleading, and crafted to deceive the public as they create an image that the Prenatal Vitamins contain "100 % [of the] recommended Daily Value of Folic Acid" and are a "complete multivitamin to help prepare for a healthy pregnancy and a healthy baby."

166. Moreover, reasonable consumers, such as Plaintiffs and Class members, would have no reason to doubt Defendants' statements regarding the amount of the Folic Acid in their Prenatal Vitamins. Defendants' misrepresentations and false statements of fact regarding the amount of Folic Acid coupled with the promotion of the Prenatal Vitamins nutritious value were intended to and did, in fact, cause consumers like Plaintiffs and the members of the Class, to

purchase products they would not have had they known the Prenatal Vitamins contained or risked containing a deficient amount of Folic Acid as compared to the amount promised on the label.

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

167. As a result of Defendants' wrongful marketing, which includes misleading, deceptive, unfair, and false statements, Defendants have generated substantial sales of the Prenatal Vitamins.

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

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

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

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

172. Although all Prenatal Vitamins contained a different amount of Folic Acid than what was stated on their labels, the One A Day Prenatal Multivitamin Tablets (60 count) contained so little Folic Acid that the ingredient was not detected. This is in sharp contrast to the amount of 800 mcg promised on the label for this Product. The One A Day Prenatal Gummies (120 count)

contained 46.66 µg of Folic Acid.[94] This is considerably less than the 800 mcg promised on the label for this Product, and is much less than the recommended daily value of Folic Acid for women who are pregnant or may become pregnant.

173. Therefore, Defendants' marketing wrongfully states their Prenatal Vitamins contain amounts of Folic Acid that is less, or at risk of being less, than the amount their Products actually contain.

174. Based on Defendants' marketing and mislabeling, a reasonable consumer would not suspect the amount of Folic Acid in the Product to be different than the amount indicated on the Product label, nor would a reasonable consumer be able to detect the actual amount of Folic Acid in the Prenatal Vitamins without conducting his or her own scientific tests or reviewing scientific testing conducted on the Products.

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

176. In light of Defendants' marketing, Defendants knew or should have known they misrepresented the amount of Folic Acid stated on the label of their One A Day products.

177. Defendants intended for consumers to rely on their marketing, and reasonable consumers did in fact so rely.

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

179. Pursuant to the foregoing, Defendants' marketing is deceptive, misleading, unfair, and false to Plaintiffs and other consumers, including under the consumer protection laws of Pennsylvania.

[94] Micrograms may be reflected as "mcg" or "µg." Plaintiffs' tests results were listed as µg.

180. Defendants acted negligently, recklessly, unfairly, and/or intentionally with their deceptive, misleading, unfair, and false marketing.

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

181. Defendants' misleading statements to consumers that their Prenatal Vitamins are nutritious and nurturing of a healthy pregnancy and provide the appropriate daily amount of vitamins and minerals violate 21 U.S.C. § 343, which provides that dietary supplements are misbranded when they contain false statements on their labels.

182. Defendants violated 21 U.S.C. § 343 by not accurately detailing that the Prenatal Vitamins contain, or risk containing, Heavy Metals. Defendants misleading marketing includes false statements that the Prenatal Vitamins contain "100% of recommended Daily Value of Folic Acid" and are a "complete multivitamin to help prepare for a healthy pregnancy and a healthy baby." These statements are false as the Prenatal Vitamins contain or risk containing undisclosed levels of Heavy Metals.

183. 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 risk containing a deficient amount of Folic Acid than was promised on the label.

184. 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

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

186. 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.

187. Defendants violated the DS CGMP rule by negligently, recklessly, and/or intentionally claiming that their Prenatal Vitamins are nutritious and nurturing of a healthy pregnancy and provide the appropriate daily amount of vitamins and minerals, by not accurately detailing that their Products contain or risk containing Heavy Metals, and by falsely representing that the Products contained a quantity of Folic Acid different than the amount the Product actually contained.

188. 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 PENNSYLVANIA LAWS

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

190. Defendants violated Pennsylvania law by negligently, recklessly, and/or intentionally claiming that their Prenatal Vitamins are nutritious and nurturing of a healthy pregnancy, provide the appropriate daily amount of vitamins and minerals, and are of "complete" to support "a healthy pregnancy and a healthy baby," and by not disclosing the presence or risk of Heavy Metals in the Products.

191. Defendants violated Pennsylvania law by negligently, recklessly, and/or intentionally claiming that their Prenatal Vitamins are nutritious and nurturing of a healthy pregnancy, provide the appropriate daily amount of vitamins and minerals, and contain "100% of

recommended Daily Value of Folic Acid" and are a "complete multivitamin to help prepare for a healthy pregnancy and a healthy baby," and by not accurately stating the quantity of Folic Acid in their Products.

192. 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.

193. Defendants have engaged in this long-term advertising campaign to convince potential customers that their Prenatal Vitamins were nutritious and nurturing of a healthy pregnancy, provided the appropriate daily amount of vitamins and minerals, 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

194. Plaintiffs reasonably relied on Defendants' claims, warranties, representations, advertisements, and other marketing concerning the particular qualities and benefits of the Prenatal Vitamins.

195. Plaintiffs read and relied upon the labels and packaging of the Prenatal Vitamins when making their purchasing decisions. Had Plaintiffs known Defendants did not disclose the presence or risk of Heavy Metals in their packaging, they would not have purchased them. Had Plaintiffs known the Prenatal Vitamins contained a misrepresentation of the quantity of Folic Acid, they would not have purchased them.

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

healthy pregnancy, provide the appropriate daily amount of vitamins and minerals, and free of the presence or risk of Heavy Metals, and that Plaintiffs were consuming the amount of Folic Acid as promised on the label.

DEFENDANTS' KNOWLEDGE AND NOTICE OF THEIR BREACHES OF THEIR IMPLIED WARRANTIES

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

198. Moreover, Defendants were put on notice by the 2008 FDA Survey about the inclusion of Heavy Metals, specifically Lead, in one of their women's vitamins and several of their children's vitamins.

199. Defendants did not change their packaging or labels to include any disclaimer that their Prenatal Vitamins contained or may contain any levels of Heavy Metals. Defendants also did not correct their packaging or labels to state the accurate amount of Folic Acid in their Prenatal Vitamins.

PRIVITY EXISTS WITH PLAINTIFFS AND THE PROPOSED CLASS

200. Defendants knew that consumers such as Plaintiffs and the proposed Class would be the end purchasers of the Prenatal Vitamins and the target of their marketing.

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

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

203. Plaintiffs and the proposed Class are the intended beneficiaries of the expressed and implied warranties.

CLASS ACTION ALLEGATIONS

204. Plaintiffs bring this action on behalf of themselves and, pursuant to Federal Rule of Civil Procedure, 23(a), (b)(2), and (b)(3), on behalf of the following Class ("the Class"). The Class is initially defined as follows:

> All persons residing in the United States or its territories who, during the maximum period of time permitted by law, purchased One A Day Prenatal Vitamins (Specifically, One A Day Prenatal with Folic Acid, DHA, and Iron, and One A Day Pre-Pregnancy Couple's Pack), manufactured by Defendants, Bayer AG, Bayer Corporation, and Bayer HealthCare LLC.[95]

205. Excluded from the Class are the 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.

206. Also excluded from the Class are any individuals or businesses who purchased the One A Day Prenatal Vitamin products for the purpose of resale.

207. 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.

208. 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.

[95] Plaintiffs reserve the right to amend this definition as necessary in accordance with applicable Federal and Pennsylvania law.

209. Questions of law and fact common to Plaintiffs 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;
(c) whether Defendants knew or should have known that the Prenatal Vitamins contained less or risked containing less Folic Acid than the amount represented on their Products' labels;
(d) whether Defendants represented and continue to represent that the Prenatal Vitamins are nutritious and nurturing of a healthy pregnancy and provide the appropriate daily amount of vitamins and minerals;
(e) whether Defendants omitted the risk of exposure to Heavy Metals and/or the presence of Heavy Metals in their Products, and/or made misrepresentations regarding quality control of their Products;
(f) whether Defendants misrepresented the quantity or amount of the ingredients, including Folic Acid, as stated on the label, and/or misrepresented the quantity or amount of the ingredients, including Folic Acid, in the formulation of their Products;
(g) whether Defendants represented and continue to represent that the manufacturing of their Prenatal Vitamins is subjected to rigorous quality standards;
(h) whether Defendants' representations in advertising, warranties, packaging, and/or labeling are false, deceptive, and misleading;
(i) whether those representations are likely to deceive a reasonable consumer;
(j) whether Defendants had knowledge that those representations were false, deceptive, and misleading;
(k) whether Defendants continue to disseminate those representations despite knowledge that the representations are false, deceptive, and misleading;
(l) whether a representation that a Product is nutritious and nurturing of a healthy pregnancy, provides the appropriate daily amount of vitamins and minerals, and does not contain or risk containing levels of Heavy Metals is material to a reasonable consumer;
(m) whether a representation that a Product provides the amount of Folic Acid stated on the label is material to a reasonable consumer;
(n) whether Defendants' marketing of the Prenatal Vitamins are likely to mislead, deceive, confuse, or confound consumers acting reasonably;
(o) whether Defendants violated Pennsylvania Unfair Trade Practices and Consumer Protection Law;
(p) whether Defendants violated 21 USC § 343;
(q) whether Defendants violated the Good Manufacturing Practices Guidelines; and
(r) whether Plaintiffs and the members of the Class are entitled to declaratory and injunctive relief.

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

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

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

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

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

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

COUNT I

(Negligent Misrepresentation Against Defendants on Behalf of the Class)

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

217. Plaintiffs reasonably placed their trust and reliance in Defendants' representations that the Prenatal Vitamins were as marketed to Plaintiffs and the Class, and were nutritious and nurturing of a healthy pregnancy and provide the appropriate daily amount of vitamins and

minerals, did not contain undisclosed levels of Heavy Metals, and contained the amount of Folic Acid as stated on the Product label.

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

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

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

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

222. As a direct and proximate result of Defendants' misrepresentations, Plaintiffs and the Class suffered actual damages in that they purchased the Prenatal Vitamins that were worth

less than the price paid and that they would not have purchased at all had they known they contained or may contain Heavy Metals that do not conform to the Products' labels, packaging, advertising, and statements, and did not contain the amount of Folic Acid promised on the Products' labels and packaging.

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

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

COUNT II

(Violations of Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. § 201, et seq. (i.e. "UTPCPL") Against Defendants on Behalf of the Class)

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

226. Plaintiffs bring this Count on behalf of themselves and the Class Members.

227. This cause of action is brought pursuant to Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. § 201, et seq. (i.e. "**UTPCPL**").

228. Pennsylvania's UTPCPL, 73 P.S. § 201-2(3), defines "trade" and "commerce" as "the advertising, offering for sale, sale or distribution of any services and any property, tangible or intangible, real, personal or mixed, and any other article, commodity, or thing of value wherever

situate, and includes any trade or commerce directly or indirectly affecting the people of this Commonwealth."

229. The UTPCPL makes it unlawful for a person or business to employ "Unfair methods of competition" and "unfair or deceptive acts or practices" by representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that he does not have. 73 P.S. § 201-2(4)(v).

230. The UTPCPL prohibits persons from employing "[u]nfair methods of competition" and "unfair or deceptive acts or practices," which are defined to include, *inter alia*, the following conduct:

a. "Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have . . . ." 73 P.S. § 201-2(4)(v); or
b. "Engaging in any other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding." 73 P.S. § 201-2(4)(xxi).

231. Defendants are defined as "persons" under the UTPCPL. 73 P.S. § 201-2(2).

232. Defendants have engaged in unfair or deceptive acts or practices in violation of UTPCPL as set forth above.

233. Defendants' practices as described herein are unfair or deceptive acts or practices that violate UTPCPL because the practices were and are intended to deceive purchasers, including Plaintiffs and Class members, and occurred and continue to occur in the course of conduct involving trade and commerce.

234. In Defendants' advertising, marketing, and sale of the One A Day prenatal vitamin products, Defendants misrepresented, and continue to misrepresent, the formulation of the products, as described more fully herein.

235. Defendants knew, or should have known, that the representations as to the formulation of the One A Day prenatal vitamin products were false, misleading, and would create a likelihood of confusion or of misunderstanding.

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

237. As alleged in the preceding paragraphs, the misrepresentations and omissions by Defendants constitutes an unfair and fraudulent business practice within the meaning of Pennsylvania UTPCPL § 201, *et seq.*

238. As a direct result of the foregoing acts and practices, the Defendants have received, continue to receive, or will receive in the future, income, profits, and other benefits, which they would not have received if Defendants had not engaged in the violations of the UTPCPL as described in this Complaint.

239. All of the conduct alleged herein occurred, and continues to occur, in Defendants' advertising, marketing, and sale of Defendants' One A Day prenatal vitamin products.

240. Pursuant to Pennsylvania UTPCPL § 201-9.2, *et seq.*, Plaintiffs and the members of the Class seek an order requiring Defendants to disclose the misrepresentations and/or omissions, and an order awarding Plaintiffs and the Class Members actual or compensatory damages, including treble damages; compelling restitution of the unnecessary financial sums wrongfully acquired by Defendants as a result of the misrepresentations and omissions; compelling the Defendants to pay civil penalties not exceeding one thousand dollars ($1,000) per violation, which civil penalty shall be in addition to other relief which may be granted; compelling the

Defendants to disgorge its ill-gotten profits; compelling the Defendants to pay the costs of the suit, including attorneys' fees; awarding Plaintiffs prejudgment interest and delay damages; and awarding Plaintiffs such other, further, and different relief as this Honorable Court may deem just.

COUNT III

(Breach of Implied Warranty of Merchantability Against Defendants on Behalf of the Class)

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

242. Defendants are merchants engaging in the sale of goods to Plaintiffs and the Class members.

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

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

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

246. Contrary to these representations and warranties, the Prenatal Vitamins were not fit for their ordinary use, consumption by women who are pregnant or may become pregnant, and did not conform to Defendants' advertisements, warranties, and representations in that they are not

nutritious and nurturing of a healthy pregnancy and provide the appropriate daily amount of vitamins and minerals, as they:

(a) Contain or risk containing undisclosed levels of Heavy Metals; and
(b) do not contain the amount of Folic Acid promised on the Product label.

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

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

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

250. Privity exists because Defendants impliedly warranted to Plaintiffs and the Class members through the warranting, packaging, advertising, marketing, and labeling that the Prenatal Vitamins were nutritious and nurturing of a healthy pregnancy and provide the appropriate daily amount of vitamins and minerals, and by failing to disclose levels or the risk of levels of Heavy Metals and misrepresenting the amount of Folic Acid in their Products.

251. As a direct and proximate result of Defendants' conduct, Plaintiffs and the Class have suffered actual damages in that they have purchased Prenatal Vitamins that are worth less than the price they paid and that they would not have purchased at all had they known the presence

or risk of Heavy Metals in the Products and that the Products contained, or risked containing, a deficient amount of Folic Acid as compared to the amount stated on the label.

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

COUNT IV

(Unjust Enrichment Against Defendants on Behalf of the Class)

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

254. 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.

255. 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.

256. 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.

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

258. 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 V

(Fraudulent Misrepresentation Against Defendants on Behalf of the Class)

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

260. Defendants falsely represented to Plaintiffs and the Class that their Prenatal Vitamins were nutritious and nurturing of a health pregnancy and provide the appropriate daily amount of vitamins and minerals.

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

262. 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.

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

264. 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.

265. As a direct and proximate result of Defendants' conduct, Plaintiffs and the Class have suffered actual damages in that they purchased 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.

266. 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 VI

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

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

268. 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 their Prenatal Vitamins did not contain the amount of Folic Acid promised on the Products' labels.

269. Defendants were under a duty to disclose to Plaintiffs and the Class the true quality, characteristics, ingredients and suitability of the Prenatal Vitamins because: (1) Defendants were in a superior position to know the true state of facts about their Products; (2) Defendants were in a superior position to know the actual ingredients, characteristics, and suitability of the Products for consumption by women who are pregnant or may become pregnant; (3) Defendants must comply with legal and regulatory guidelines; and (4) Defendants knew that Plaintiffs and the Class

could not reasonably have been expected to learn or discover that the Products were misrepresented in the packaging, labels, advertising, and websites prior to purchasing the Products.

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

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

272. 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 Heavy Metals that do not conform to the Products' labels, packaging, advertising, and statements, and had they known the Prenatal Vitamins contained, or had a risk of containing, a deficient amount of Folic Acid as compared to the amount stated on the Product label.

273. Plaintiffs and the Class seek actual damages, injunctive and declaratory relief, 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 nutritious and nurturing of a healthy pregnancy and provide the appropriate daily amount of vitamins and minerals;

F. An order requiring Defendants to engage in a corrective advertising campaign and engage in any further necessary affirmative injunctive relief, such as recalling 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 Trade Practices and Consumer Protection Law, 73 P.S. § 201, et seq. (i.e. "UTPCPL"), 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;

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

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

JURY DEMAND

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

Respectfully submitted,

Anna Kharaeva and Zsaiahna Huff,
individually and on behalf of all others similarly situated,

Joshua M. Neumann

Dated: February 18, 2021

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**Pro Hac Vice* admission to be sought