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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

LIZA GERSHMAN, On Behalf of Herself and All Others Similarly Situated, Plaintiff, v. BAYER HEALTHCARE, LLC, a Delaware Limited Liability Company, Defendant.	Case No.: **CLASS ACTION COMPLAINT FOR:** 1. VIOLATION OF THE UNFAIR COMPETITION LAW, Business and Professions Code §17200 *et seq.*; and 2. VIOLATION OF THE CONSUMERS LEGAL REMEDIES ACT, Civil Code §1750 *et seq.* DEMAND FOR JURY TRIAL

Plaintiff Liza Gershman brings this action on behalf of herself and all others similarly situated against Defendant Bayer Healthcare, LLC ("Bayer" or "Defendant") and states:

NATURE OF ACTION

1. In or around August 2013, Bayer began manufacturing, marketing, selling and distributing Flintstones Healthy Brain Support, a gummy-chewable Omega-3 DHA dietary supplement made with Life's DHA ("the Product"). The Product is not a multivitamin. The Product's sole represented benefits are to provide brain function benefits and brain support benefits. The Product is for adults and children two years and older.

2. Through an extensive, widespread, comprehensive and uniform nationwide marketing campaign, Bayer claims that consuming the Product will "Support[] Healthy Brain Function". On each and every package immediately under the Product name it states "Healthy" above the phrase "BRAIN SUPPORT" (the latter being in a much larger font). In a separate box below this quoted language is the representation that "Omega-3 DHA Supports Healthy Brain Function."[1]

3. Experts in the field determine whether a substance provides brain function benefits by performing randomized controlled clinical trials ("RCTs") and measuring whether, in comparison to placebo, it provides improved cognitive function.

4. Here, the only ingredient in the Product that purportedly provides any brain health benefits is the 50mg-100mg of Omega-3 DHA in each daily dose.[2] Thus, whether Flintstones Healthy Brain Support supports brain function is to be determined by the results of RCTs that have tested Omega-3 DHA. As more fully set forth below, RCTs have conclusively shown that algal Omega-3 DHA

[1] The other ingredients are sugars and a miniscule amount of vitamin C – 2% of the minimum daily value.

[2] 50 mg is the recommended daily dose for children 2 and 3 years of age and 100mg is the recommended daily dose for those 4 years of age and older.

supplements such as the Flintstones Healthy Brain Support supplements sold by Defendant, do not improve cognitive development. And, the scientific evidence is clear that Omega-3 DHA supplementation does not provide any brain function benefits.

5. By law, the FDA does not and cannot regulate the pre-market approval of health benefit statements about dietary supplements such as Flintstones Healthy Brain Support. Instead, it is the manufacturer's responsibility to ensure that the statement "characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function…." and that the manufacturer "has substantiation that such statement is truthful and not misleading." 21 U.S.C. §343(r). As more fully set forth herein, the brain function and brain support representations do not have a "documented mechanism by which" the algal Omega-3 DHA in the Product acts to provide these benefits. Moreover, rather than having adequate substantiation for its brain function and brain support representations, the scientific evidence is clear that algal Omega-3 DHA supplementation does not provide brain function or brain support benefits.

6. The Flintstones Healthy Brain Support label – in smaller print – on the side of the bottle – carries a required "disclaimer" that the Product is not "intended to diagnose, treat, cure or prevent any disease." This disclaimer language is required when a dietary supplement manufacturer makes a "structure/function" claim, such as Defendant has made here.

7. This disease disclaimer has no impact on the representations being challenged. The FDA regulations distinguish between "structure/function claims" – such as the brain support/function claims Bayer makes – and "disease claims" which require pre-market approval from the FDA. *See* FDA, Guidance for Industry: Structure/Function Claims, Small Entity Compliance Guide, http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInfo

rmation/ucm103340.htm.

8. As more fully set forth below, the results from five RCTs involving the *same* algal Omega-3 DHA as is in the Product show that Omega-3 DHA algal oil supplementation performs no better than placebo with regard to brain function. This was so even though several of these RCTs were funded by the manufacturer of the Life's DHA which is used in the Product and even though the studies evaluated much higher doses of DHA than that found in the Product (at least eight times the amount of DHA as the recommended dosage of the Product for children 2-3 years old and 4 times the amount in the recommended dosage for adults and children 4 years and older).

9. Further, it makes no difference that the studies did not employ DHA delivered in a gummy as opposed to a pill. Once digested, the DHA that remains is the same from either delivery vehicle.

10. Equally important to the results of the five RCTs finding no brain function benefits from algal DHA supplementation, is the fact that the algal oil derived DHA in the Product is superfluous as it is not used by the body once consumed, making it useless for any brain function or brain support benefit. In this regard, the scientific evidence shows that the body manufactures DHA from other readily available fatty acids derived from a variety of dietary sources. Thus, American children and adults, who are the target market for the Product, consume adequate amounts of DHA in their diet. There is no need for anyone to take a DHA supplement - their bodies make the needed amounts of DHA.

11. For example, the Institute of Medicine ("IOM")—the health arm of the National Academies—has issued a report stating that it does not recognize a dietary requirement for DHA as there is no DHA deficiency in adults or children in the United States. *See* Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients): The National

Academies Press; 2005 at 5-6, 11, 469.

12. On April 22, 2014, the FDA embraced the IOM finding by publishing a Final Rule that acted on and expressly rejected Martek Biosciences Corp.'s (the maker of the Life's DHA in Bayer's Product) request that the FDA recognize a daily requirement for DHA. *See* http://www.gpo.gov/fdsys/pkg/FR-2014-04-28/pdf/2014-09492.pdf. In doing so, the FDA acknowledged that there is no dietary requirement for DHA as it is not an essential nutrient. *Id*. That is why there is no daily value listed on the Product label.

13. Moreover, only a trivial amount of the DHA in the Product ever enters the brain after it is consumed. The brain contains about 5000 mg of DHA. A daily dose of the Product would only provide about .000005% and .00001% of the brain's DHA content in children 2-3 years of age and adults and children over 4, respectively. This amount is so trivial that experts in the field can conclude, on this basis alone, that the DHA contained in the Product cannot and does not support the brain or its functioning in any manner.

14. Thus, the overwhelming weight of scientific evidence is that DHA supplementation does not provide brain function benefits and does not provide brain support. The only ingredient in the Product represented as providing brain support or function is the DHA. Thus, Bayer's brain function and brain support representations are false, misleading, and reasonably likely to deceive the public.

15. Defendant's brain support and brain function representations are also unlawful. Flintstones Healthy Brain Support is a dietary supplement. 21 U.S.C. § 321(g)(d). Dietary supplements are regulated under the Dietary Supplement Health and Education Act of 1994 ("DSHEA"). Manufacturers are not required to get FDA approval before producing or selling a dietary supplement. However, manufacturers must make sure that all health benefit claims on the product package and label are truthful and not misleading. With regard to each of the representations Defendant

makes about Flintstones Healthy Brain Support, this means that Defendant is required to make sure the they are truthful and not misleading.

16. In order to be truthful and not misleading, dietary supplement health benefit claims must be substantiated by competent and reliable scientific evidence. 21 U.S.C. § 321(r)(6)(b); Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r) (6) of the Federal Food, Drug, and Cosmetic Act, ("FDA Guidance of Industry"), Ex. A.

17. Under DSHEA, competent and reliable scientific evidence is defined as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." FDA Guidance of Industry, Ex. A.

18. Experts in the field, as well as experts in other fields that concern substances that purport to provide human health benefits, deem the only credible scientific evidence to substantiate human health benefit claims, such as those at issue here, is evidence from RCTs (hereafter "competent and reliable evidence"). No such RCTs exist to substantiate the brain support and brain function representations made by Defendant about Flintstones Healthy Brain Support.

19. Because there is no competent and reliable evidence that Flintstones Healthy Brain Support provides brain support or brain function benefits, Defendant is selling a dietary supplement in violation of federal law, DSHEA, and California's Sherman Act.

20. Bayer has employed numerous methods to convey its uniform, deceptive brain function and brain support representations to consumers including the name of the Product and the front of the Product's packaging and labeling where they cannot be missed by consumers.

21. As a result of Bayer's deceptive brain function and brain support representations, consumers—including Plaintiff and members of the proposed Class—have purchased the Product, which does not perform as advertised. The only reason a consumer would purchase the Product is to obtain the advertised brain function and brain support benefits because these are the only stated benefits of the Product.

22. Plaintiff brings this action on behalf of herself and other similarly situated consumers who have purchased Flintstones Healthy Brain Support to halt the dissemination of these false, misleading and deceptive advertising messages, correct the false and misleading perception it has created in the minds of consumers, and obtain redress for those who have purchased the Product. Based on violations of state unfair competition laws (detailed below), Plaintiff seeks injunctive and monetary relief for consumers who purchased the Product.

23. Plaintiff also brings this action on behalf of herself and other similarly situated California consumers who have purchased Flintstones Healthy Brain Support, under the "unlawful" prong of the UCL. Plaintiff seeks to halt Defendant's unlawful sale of Flintstones Healthy Brain Support in violation of applicable FDA law and regulations and California's Sherman Act and also seeks full restitution of Plaintiff's and other California consumers' full purchase price.

JURISDICTION AND VENUE

24. This Court has original jurisdiction pursuant to 28 U.S.C. §1332(d)(2). The matter in controversy, exclusive of interest and costs, exceeds the sum or value of $5,000,000 and is a class action in which there are in excess of 100 class members and Class members are citizens of a state different from Defendant.

25. This Court has personal jurisdiction over Defendant because Defendant is authorized to conduct and does conduct business in California. Defendant has marketed, promoted, distributed, and sold the Product in California and Defendant

has sufficient minimum contacts with this State and/or sufficiently availed itself of the markets in this State through its promotion, sales, distribution and marketing within this State to render the exercise of jurisdiction by this Court permissible.

26. Venue is proper in this Court pursuant to 28 U.S.C. §1391 because a substantial part of the events giving rise to Plaintiff Gershman's claims occurred while she resided in this judicial district. Venue is also proper because Defendant transacts substantial business in this District.

PARTIES

27. Plaintiff Liza Gershman is a citizen of California and resides in San Francisco, California. In or around the summer/spring of 2014, Plaintiff Gershman purchased one bottle of Flintstones Healthy Brain Support from Walgreens in San Francisco, California. Prior to purchasing the Product, Plaintiff Gershman was exposed to and saw Bayer's brain function and brain support representations by reading the Product's label. Plaintiff Gershman purchased the Product in reliance on Bayer's brain function and brain support representations. Plaintiff paid approximately $15.00 for the Product. The Product Plaintiff Gershman purchased has been proven to not support healthy brain function and the scientific evidence is that taking Defendant's DHA supplement does not provide brain support. As a result, Plaintiff Gershman suffered injury in fact and lost money at the point when she purchased the Product. Had Plaintiff Gershman known the truth about Bayer's misrepresentations, she would not have purchased the Product.

28. Defendant Bayer Healthcare, LLC is a Delaware limited liability company with its principal place of business in Whippany, New Jersey. The sole member of Bayer Healthcare, LLC is Bayer Corporation. Bayer Corporation is an Indiana corporation with its principal place of business in Pennsylvania. Defendant is therefore a citizen of Delaware, Indiana and Pennsylvania.

29. At all relevant times, Defendant manufactured, distributed, marketed

and sold the Product and created the deceptive brain function and brain support representations, which it caused to be disseminated to consumers throughout the United States, including California.

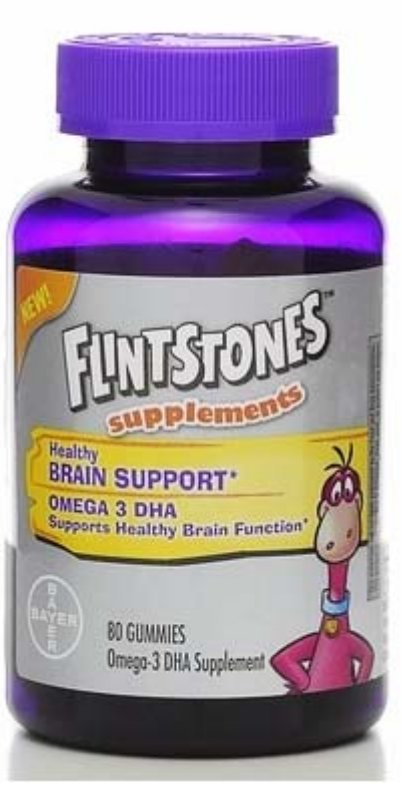
FACTUAL ALLEGATIONS

Flintstones Healthy Brain Support

30. Since at least August 2013, Bayer has manufactured, distributed, marketed and sold the Product throughout the United States, including California. The Product is marketed as a supplement with the singular purpose of providing brain function benefits and brain support benefits. The Product is sold in virtually every major food, drug, and mass retail outlet in the country, and retails for approximately $13-$16 for 80 gummies. Each gummy contains 50 mg of DHA - children ages 2-3 are directed to take 1 gummy daily (*i.e.*, 50 mg DHA daily) and adults and children ages 4 and older are directed to take 2 gummies daily (*i.e.*, 100 mg DHA daily).

31. Since the Product's launch, Bayer has consistently conveyed the message to consumers throughout the United States, including California, that the Product provides "Healthy Brain Support" and "Supports Healthy Brain Function." Bayer's brain function and brain support representations are false, misleading and deceptive.

32. Each and every consumer who purchases the Product is exposed to Bayer's deceptive brain function and brain support representations, which are the only represented Product benefits and appear prominently and conspicuously on the front of the Product's packaging, as follows:



The Product Does Not Provide Healthy Brain Support and Does Not Support Healthy Brain Function

33. DHA is a long-chain Omega-3 fatty acid typically found in cold water fish. The DHA in Bayer's Product is not derived from fish. Instead, the Life's DHA in the Product -- manufactured by Martek Biosciences -- is from algae. Contrary to Bayer's representations made on each and every Product package, DHA algal oil does not support healthy brain function or provide brain support.

34. The results from several RCTs, regarded by experts in the field as the "gold standard" of scientific evidence, show that the DHA in the Product provides no brain function benefits, even though these studies involved far higher amounts of DHA supplementation.

35. For example, a 2008 RCT funded by Martek Biosciences, the manufacturer of the Life's DHA in the Product – examined algal DHA supplementation (400mg) in 4-year old children for 16 weeks and reported no effect

of DHA on 4 measures of cognitive function in children: "[t]he results did not demonstrate statistically significant improvements in cognitive measures." *See* Ryan, A., et al., *Assessing The Effect Of Docosahexaemoic Acid On Cognitive Functions In Healthy Preschool Children*, 47(4) Clin. Pediatr. 355-62 (2008). Indeed, the authors acknowledged "the primary end points[3] of the study were not met." This is so even though the amount administered was 400mg or 4 times the daily dose of the Product for persons over four years of age. Furthermore, in attempting to explain away the negative results, the authors noted that perhaps an even "larger dose" of DHA might be required to possibly see any results.

36. *Ryan et al.*, also included the results of a secondary analysis where they ran regression analyses of the test results against DHA levels in the blood. The report states that this was done with regard to both the DHA group and the placebo group as to all four tests. But the results for only one test, the PPVT test, and one group, the DHA group, were reported. There is no explanation why the results from the regression analyses for the other tests for both the DHA group and placebo group were not reported. Nor, is there any explanation why the results for both the placebo group and the PPVT test were not reported in order for a comparison between placebo and DHA groups for this test.

37. As a threshold matter, the use of regression analyses, such as the one performed in *Ryan et al.*, are not considered the type of statistical analysis that is acceptable for reaching any cause and effect conclusions. This is particularly true with regard to DHA blood levels, which can vary widely from individual to individual over time.

38. Yet, as reported in *Ryan et al.*, for one group, the DHA group who gave

[3] The primary outcome measured attention, memory, processing, speed and error rate. *Id.* at 2.

blood samples at both the beginning and end of the study,[4] with regard to one of the four tests used to measure cognitive performance, there was a positive correlation between DHA blood levels and test results. While the authors stated that they were going to perform this analysis on all four tests, the results of the blood level regression analysis with the three other tests were not reported. Thus, it is safe to assume that these results were null or negative, since, while stating that they ran regressions for blood levels for all four of the tests, *Ryan et al*. does not report these other results.

39. The study's authors stated that this secondary analysis was preplanned ("The relationship between blood DHA levels and the efficacy end points were considered preplanned secondary outcomes."). However, at clinicaltrials.gov, where the protocol of this study was registered,[5] this particular secondary analysis was not described. Instead, the secondary endpoints are safety and a simple measurement of DHA blood levels before and after DHA supplementation without any mention of a regression analysis being performed.

40. Under accepted scientific conventions, unless an endpoint, be it primary or secondary, is described in the registration, it is not deemed an endpoint from which any conclusions can be drawn.

41. Further, nowhere in their registration do the authors describe an intention to perform a regression analysis solely on the DHA treatment group.

42. Moreover, the number of subjects within the DHA blood level study group are internally inconsistent and raise considerable doubt about the accuracy of this, albeit, secondary and exploratory analysis. First, there are 46 subjects described as being in the DHA blood level group. The authors then excluded, albeit for an

[4] As the report notes, because of some children's unwillingness to have their fingers stuck with a pin to draw blood, this was a smaller subset than the subjects who merely took placebo or 400mg of DHA and took the tests.

[5] Most studies that are conducted with the intention of potential publication in a peer-reviewed journal register the protocol of the study and its general progress to completion. The registration for this study can be found at https://clinicaltrials.gov/ct2/show/NCT00351624?term=Docosahexaenoic+and+ryan&rank=1.

improper reason, four subjects in the DHA blood level group.[6] And then, in figure 1 in the study report, which purports to depict the results of the regression analysis, there are only 40 points plotted on the graph, reflecting yet another inexplicable exclusion of two more subjects. Putting aside all of the other irregularities with regard to this secondary analysis, these numerical inconsistencies, on their own, cause whatever conclusions that might have been drawn from this secondary/exploratory analysis to be suspect and not reliable to reach any cause and effect conclusions.

43. This secondary analysis only shows results for the DHA group. Yet, only analyses that compare results between an active ingredient and placebo group can result in cause and effect conclusions. Here, this secondary analysis was merely a within group comparison of DHA blood levels and test scores within one group, the DHA group.

44. Even if a comparison of regression analyses within groups had been performed, correlations of the sort that were performed in this secondary analysis cannot be used to reach cause and effect conclusions. At best, such correlation analyses can produce hypotheses that require subsequent testing through RCTs.

45. Moreover, even if this correlation could be deemed a positive result, which it cannot, it is an accepted convention among experts in the field that in interpreting the results of a study such as this one, where multiple tests/measures/endpoints are employed, the existence of one positive result within numerous negative results still means that the results of study have shown that the substance being studied is no better than placebo. In other words, it is improper, under accepted scientific conventions in interpreting results of clinical studies such as this one where multiple tests are employed, to cherry pick individual results and,

[6] They state that these subjects were excluded because their DHA levels did not go up even though they were taking the supplement. This is not a valid reason to exclude these subjects in the intent to treat design that the authors claimed that they were following.

instead, one must view the results of each study as a whole.

46. Furthermore, under standard scientific conventions of interpreting results from RCTs, this one secondary analysis (if it even was pre-planned, which it was not), must be read in the context of the results of the primary endpoints in which it was clearly found that DHA was no better than placebo with regard to cognitive function. Under accepted scientific conventions, experts in the field would deem the results of this study to show that DHA supplementation of 400mg per day was no better than placebo in supporting brain function and this, in fact, is the conclusion of the authors where they state: "For each test, results indicated that changes from baseline to end of treatment were not statistically significantly different between the docosahexaenoic acid group and the placebo group."

47. Even the authors of the *Ryan et al*. study, whose lead investigator was employed by Martek, were constrained about the conclusions to be drawn from this secondary analysis on blood levels and only stated: "That healthy children *may* benefit from DHA supplementation is promising" (emphasis added). In other words, this secondary analysis could not be relied upon to reach the conclusion that DHA was proven to and *did* provide a benefit to healthy children.

48. As a result, following accepted conventions of study result interpretation, these Martek employed authors were constrained to conclude "further studies are needed to further elucidate the effects of DHA supplementation on cognitive function in healthy children." This is because even though this regression analysis may have found a correlation between high DHA levels and test results in the DHA group, the fact still remains that the test scores of the DHA group were no better than the placebo group (the primary endpoint of the study).

49. Thus, this secondary analysis, at best, under accepted scientific principles, was an exploratory analysis and could not and should not be deemed one upon which cause and effect conclusions can be made.

50. In a 2009 RCT, David Kennedy and colleagues examined the effects of 400 or 1000 mg[7] of DHA per day compared to placebo on a battery of cognitive tests in children ages 10 to 12. *See* Kennedy, DO, et al., *Cognitive And Mood Effects Of 8 Weeks' Supplementation With 400 Mg Or 1000 Mg Of The Omega-3 Essential Fatty Acid Docosahexaenoic Acid (DHA) In Healthy Children Aged 10–12 Years*, 12 Nutr. Neurosci. 48-56 (2009). At a dose of 400 mg per day, scores on 1 of 35 measures improved while 1 score out of 35 was worse upon 1000 mg per day, and no effect was observed on 68 other measures. *Id.* Because so many tests were conducted, with regard to the one positive and the one negative finding the authors appropriately concluded that these two outlier results were due to chance and that the 34 results that showed no effect by their sheer weight were not due to chance and demonstrated a lack of efficacy. *Id.* Thus, the authors concluded: "The results here do not suggest that supplementation with these doses of DHA for 8 weeks has any beneficial effect on brain function in cognitively intact children." *Id.*[8]

51. Similarly, a RCT reported by McNamara, RK, et al., *Docosahexaenoic Acid Supplementation Increases Prefrontal Cortex Activation During Sustained Attention In Healthy Boys; A Placebo-Controlled, Dose-Ranging, Functional Magnetic Resonance Imaging Study*, 91 Am. J. Clin. Nutr., 1060-7 (2010), examined the effect of 400 or 1200[9] mg DHA per day compared to placebo on attention scores in healthy boys. For the one primary registered endpoint "performance on sustained attention task"[10] (that was measured four ways), McNamara and colleagues reported

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[7] Four to ten times the recommended daily dose of the Product.

[8] The *Kennedy* study also examined whether DHA supplementation had any consistent or meaningful effect on mood in children ages 10-12. The study's authors concluded that it did not. *Id.* at 54, 55-56.

[9] Four times and twelve times the daily recommended dose of the Product.

[10] See https://clinicaltrials.gov/ct2/show/NCT00662142?term=mcnamara+and+martek&rank=1. As noted above, every clinical trial that is registered at clinicaltrial.gov, must set forth, among other things, the endpoints that the study is designed to examine. Under universally accepted scientific protocols, conclusions can only be drawn from the results of the registered endpoints.

no effects of DHA on all 4 measures at either the 400mg or 1200mg doses.

52. The study also measured whether DHA supplementation increased brain activation. The results showed for the DHA group as compared to the placebo group increased activation in the dorsal lateral prefrontal cortex and pre-central gyrus, but decreases in the bilateral occipital cortex. While this may have been an observed effect, it is of no meaning in the context of whether DHA provides any brain health benefits because, notwithstanding this reported increased activation, the subjects taking DHA did not perform any better on the cognitive testing than did those given placebo.

53. Finally, in a 2012 RCT, Alexandra Richardson and colleagues examined placebo or 600 mg[11] of DHA per day for 16 weeks in school children ages 7 to 9 who were under the 33rd percentile in reading scores. *See* Richardson, AJ, et al., *Docosahexaenoic Acid For Reading, Cognition And Behavior In Children Aged 7–9 Years: A Randomized, Controlled Trial (The DOLAB Study)*, PLoS One, 7:e43909 (2012). As set forth in the study report, the original protocol for the study was to select children in the twentieth or below percentile in reading, but because they could not recruit enough subjects for the study to be adequately powered, they raised the inclusion criteria to the 33% percentile or below. The results of the study, as registered and designed by its authors, concluded that there were no differences between DHA and placebo on reading scores, reading age, two working memory scores or 14 behavior scores whether rated by parents, teachers or using intent-to-treat (all subjects) or per protocol design (only those who completed the study). *Id.* Thus, this study showed no efficacy.

54. The report proffers a purported secondary analysis on results for those subjects that were in the twentieth percentile or below. This analysis was not a registered endpoint with clinicaltrials.gov and thus, cannot be deemed an endpoint

[11] Six times the recommended daily dose of the Product for adults and children 4 and older.

upon which cause and effect conclusions can be reached. Further, the authors did not find sufficient subjects in the twentieth percentile to conduct an adequately powered study – a requirement for drawing any cause and effect conclusions. As a result, any conclusions derived from the subset of twentieth percentile or below subjects can only be deemed hypotheses for further study and cannot serve as a basis for cause and effect conclusions. This is due to the fact that when a study or subgroup analysis is not adequately powered, it is accepted by experts in the field that any such results can also be due to chance.

55. As noted above, all of the RCTs using the DHA in the Product, while in far larger doses, showed no brain function benefits. Furthermore, while all of these studies that showed no effect were on healthy children, the results of these studies can be and are used to extrapolate to healthy adults by experts in the field. This is due to the fact that adults are no longer accreting DHA in their brains, and the scientific evidence is that as humans age their need for DHA decreases over time (e.g., pre-natal and up to age 2 DHA has been shown to provide brain health benefits, but no effects have been shown after the age of 2).

56. These scientific studies establish that there is no cause and effect relationship between intake of DHA dietary supplements like the DHA in Bayer's product and brain function. Thus, Bayer's brain function representations are false and misleading and reasonably likely to deceive the consumer.

57. In addition to, and separately from, the evidence from RCTs, the Product cannot support brain function or brain support because: (1) a trivial and meaningless amount of DHA is provided to the brain by the Product; and (2) American children and adults get sufficient DHA in their daily diet.

58. While *molecular* DHA does play a role in the brain, this does not mean *supplemental* DHA supports brain function. Much as the brain needs oxygen to function, humans do not need to supplement their diets with oxygen; nor do humans

need DHA supplementation. In fact, there is only one reported case of Omega-3 deficiency in the United States in the last thirty years and it involved a girl on an intravenous diet.

59. In this regard, it should also be understood that the human body produces DHA from other Omega-3 fatty acids that are consumed on a daily basis. As result, the target population for this Product produces sufficient amounts of DHA from a variety of dietary sources, even if they do not consume dietary DHA from such foods as fish rich in DHA.

60. Furthermore, a trivial amount of the DHA in a daily dose of the Product actually enters the brain – so small that experts in the field deem this amount as incapable of providing any brain function or brain support benefit. Based on the amount of DHA available to the brain in the plasma pool and the amount of DHA the brain uptakes from this plasma pool, it is estimated that approximately 0.0005% of an oral dosage enters the brain in 24 hours. And, because the brain contains about 5000 mg of DHA, a daily dose of the Product would only replace about .000005% and .00001% of the brain's DHA content in children 2-3 years of age and adults and children over 4, respectively, on a daily basis. While these estimates may vary as much as 10-100 times in either direction, even at the highest point in the estimate range (e.g. 100 x .00001% or .00100%), experts in the field deem this amount of DHA to be trivial and that it cannot contribute to brain function or brain support.

61. In this vein, the IOM—the health arm of the National Academies—has issued a report stating that it does not recognize a dietary requirement for DHA as there is no DHA deficiency in adults or children in the United States. *See* Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients): The National Academies Press; 2005 at 5-6, 11, 469. Specifically, the IOM concluded that Americans consume sufficient amounts of alpha-linolenic acid (ALA), a dietary precursor to DHA, in their daily

diet. ALA is converted to DHA by a series of enzymes, largely in the liver. Thus, the algal oil derived DHA in the Product has no effect on brain function or brain support as it is not an essential nutrient and American adults and children are already producing adequate amounts of DHA from its dietary precursor ALA.

62. Likewise, on April 22, 2014, the FDA, citing the 2005 IOM report, published a Final Rule that acted on and expressly rejected Martek Biosciences Corp.'s (the maker of the DHA in Bayer's Product) request that the FDA recognize a daily requirement for DHA.[12] *See* 79 Fed. Reg. 23262 *available at* http://www.gpo.gov/fdsys/pkg/FR-2014-04-28/pdf/2014-09492.pdf. In doing so, the FDA acknowledged that there is no dietary requirement for DHA as it is not an essential nutrient. *Id.* The FDA's ruling applies to the entire U.S. population, including adults and children ages 2 years and older – Bayer's target market for the Product.

63. In sum, the DHA in the Product is superfluous and does not provide brain function or brain support benefits because: a) DHA is not an essential nutrient; b) Americans already get plenty of DHA in their diet; c) there are virtually no reported cases of a DHA deficiency in the United States; d) basic chemistry and biology show that the human body makes sufficient DHA by converting a different substance, ALA, into DHA; and e) the amount of DHA in Flintstones Healthy Brain Support is trivial and incapable of supporting brain function or brain support

64. Thus, the overwhelming weight of scientific evidence is that the DHA in a daily dose of Defendant's Product does not support brain function or provide brain support in U.S. consumers aged 2 and older.

Defendant is Unlawfully Selling Flintstones Healthy Brain Support in Violation of Federal and State Law

[12] The Martek notification proposed the following exact wording for these claims: "'Excellent source of DHA.' ('High in DHA,' 'Rich in DHA') contains ___ mg of DHA per serving, which is ___ % of the 160 mg daily value for DHA." 79 Fed. Reg. at 23263 n.3.

65. Flintstones Healthy Brain Support is a dietary supplement and governed by DSHEA.

66. DSHEA permits the makers of dietary supplements to make claims as to how their supplement affects the structure or function of the body without obtaining prior FDA approval provided certain requirements are met. 21 U.S.C. §§342, 343. One of these requirements is that the manufacturer must have substantiation that the claims are truthful and not misleading. 21 U.S.C. §343(r)(6)(B).

67. California's Sherman Food, Drug, and Cosmetic Law ("Sherman FD&C") (California's Health & Safety Code §§109875, et. seq.), parallels the FDCA in material part and adopts the Federal requirements for dietary supplements, including that dietary supplement claims be made in accordance with Section 403(r)(6) of the FDCA. Cal. Health & Safety Code § 110100(a).

68. The FDA has adopted the FTC's substantiation standard of "competent and reliable scientific evidence" for dietary supplements as described above.

69. Competent and reliable scientific evidence is defined as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." FDA Guidance of Industry, Ex. A. For products such as Flintstones Healthy Brain Support, adequate substantiation as required by experts in the relevant area consists of high quality RCTs.

70. There are no reliable or high quality RCTs substantiating any of the representations made by Defendant about Flintstones Healthy Brain Support.

71. By selling Flintstones Healthy Brain Support without the prerequisite competent and reliable scientific evidence/substantiation for these representations, Defendant has violated DSHEA and the Sherman Law.

The Impact of Bayer's Wrongful Conduct

72. Even though the DHA in the Product is trivial in amount, superfluous, and proven to not support healthy brain function, Bayer continues to unequivocally claim that its Product provides "brain support" and "Supports Healthy Brain Function" in children ages 2 and older, as well as adults.

73. Plaintiff and Class members have been and will continue to be deceived or misled by Bayer's deceptive brain function and brain support representations. Plaintiff purchased the Product during the relevant time period and in doing so, read and considered the Product label and based her decision to buy the Product on the brain function and brain support representations. Bayer's brain function and brain support representations were a material factor in influencing Plaintiff's decision to purchase the Product. Plaintiff would not have purchased the Product had she known that Bayer's brain function and brain support representations were false and misleading.

74. As a result, Plaintiff and the Class members have been damaged in their purchases of the Product and have been deceived into purchasing a Product that they believed, based on Bayer's representations, provides brain function benefits and brain support benefits, when, in fact, it does not.

CLASS DEFINITION AND ALLEGATIONS

75. Plaintiff Gershman brings this action on behalf of herself and all other similarly situated Class members pursuant to Rule 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure and seeks certification of the following Class against Defendants for violations of California state laws and/or similar laws in other states:

> **Multi-State Class Action**
> All Consumers who, within the applicable statute of limitations period, purchased Flintstones Healthy Brain Support in California, Massachusetts, Michigan, Minnesota, Missouri, New Jersey, New York, and Washington until the date notice is disseminated.

> Excluded from this class are Defendant and its officers, directors, and employees and those who purchased Flintstones Healthy Brain Support for re-sale.

76. Alternatively, Plaintiff Gershman brings this action on behalf of herself and all other similarly situated California consumers pursuant to Rule 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure and seeks certification of the following Class:

> **California-Only Class Action**
> All California consumers who, within the applicable statute of limitations, purchased Flintstones Healthy Brain Support until the date notice is disseminated.
>
> Excluded from this Class are Defendant and its officers, directors and employees, and those who purchased Flintstones Healthy Brain Support for the purpose of resale.

77. **Numerosity.** The members of the Class are so numerous that joinder of all members of the Class is impracticable. Plaintiff is informed and believes that the proposed Class contains thousands of purchasers of Flintstones Healthy Brain Support who have been damaged by Bayer's conduct as alleged herein. While the exact number and identities of the Class members are unknown at this time, such information can be ascertained through appropriate investigation and discovery.

78. **Existence and Predominance of Common Questions of Law and Fact**. This action involves common questions of law and fact, which predominate over any questions affecting individual Class members. These common legal and factual questions include, but are not limited to, the following:

(a) whether the claims discussed above are false, or are misleading, or likely to deceive;

(b) whether Bayer's alleged conduct violates public policy;

(c) whether the alleged conduct constitutes violations of the laws asserted;

(d) whether Bayer engaged in false or misleading advertising; and

(e) whether Plaintiff and Class members are entitled to other appropriate remedies, including corrective advertising and injunctive relief.

79. ***Typicality.*** Plaintiff's claims are typical of the claims of the members of the Class because, *inter alia*, all Class members were injured through the uniform misconduct described above and were subject to Bayer's deceptive brain function/support representations that accompanied each and every bottle of Flintstones Healthy Brain Support. Plaintiff is advancing the same claims and legal theories on behalf of herself and all members of the Class.

80. ***Adequacy of Representation***. Plaintiff will fairly and adequately protect the interests of the members of the Class. Plaintiff has retained counsel experienced in complex consumer class action litigation, and Plaintiff intends to prosecute this action vigorously. Plaintiff has no adverse or antagonistic interests to those of the Class.

81. ***Superiority***. A class action is superior to all other available means for the fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by individual Class members is relatively small compared to the burden and expense that would be entailed by individual litigation of their claims against Bayer. It would thus be virtually impossible for Plaintiff and Class members, on an individual basis, to obtain effective redress for the wrongs done to them. Furthermore, even if Class members could afford such individualized litigation, the court system could not. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase the delay and expense to all parties and the court system from the issues raised by this action. By contrast, the class action device provides the benefits of adjudication of these issues in a single proceeding, economies of scale, and comprehensive supervision by a single court, and presents no unusual management difficulties under the circumstances here.

82. Plaintiff seeks preliminary and permanent injunctive and equitable relief on behalf of the entire Class, on grounds generally applicable to the entire Class, to enjoin and prevent Bayer from engaging in the acts described, and requiring Bayer to provide full restitution to Plaintiff and Class members.

83. Unless a Class-wide injunction is issued, Bayer will continue to commit the violations alleged, and the members of the Class and the general public will continue to be deceived.

84. Bayer has acted and refused to act on grounds generally applicable to the Class, making appropriate final injunctive relief with respect to the Class as a whole.

COUNT I
Violation of Business & Professions Code §17200, *et seq.*
(On Behalf of the California-Only Class)

85. Plaintiff Gershman repeats and re-alleges the allegations contained in the paragraphs above, as if fully set forth herein.

86. Plaintiff Gershman brings this claim individually and on behalf of the California-only Class.

87. The Unfair Competition Law, Business & Professions Code §17200, et seq. ("UCL"), prohibits any "unlawful" business act or practice.

88. As alleged herein, Defendant engaged in illegal conduct by unlawfully making the representations set forth above. Because Defendant did not have adequate substantiation that these representations were truthful and not misleading Defendant has committed unlawful business practices by violating California's Sherman Food, Drug and Cosmetic Law, California's Health & Safety Code §§ 109875, et seq. and the Food Drug and Cosmetic Act, 21 U.S.C. §§ 301, et seq. Plaintiff and the California-only Class reserve the right to allege other violations of law, which constitute other unlawful business acts or practices. Such conduct is ongoing and continues to this date.

89. Plaintiff and the California-only Class suffered "injury in fact"/economic loss by spending money on a Product that, but for Defendant's illegal conduct, would not have been on the market.

90. The FDA and Sherman Act misbranding/consumer protections are intended to ensure that any claims made about dietary supplements, as defined under the FDA law and regulations, to the consuming public (e.g., sold to Plaintiff and the Class), are truthful and not misleading.

91. The UCL unlawful prong is intended to hold a defendant who violates this prong accountable for its violations by, among other things, paying full compensation to purchasers who have purchased the illegally sold products.

92. But for Defendant unlawfully selling Flintstones Healthy Brain Support, Plaintiff and the California-Only Class would never have purchased this illegal Product. As result of Defendant's illegal conduct, Plaintiff and the California-Only Class have suffered injury/economic loss and are entitled to a full refund of their purchase price. Unless restrained and enjoined, Defendant will continue to engage in the illegal sale of the Product. Accordingly, injunctive relief is appropriate

93. Plaintiff, on behalf of herself, all other similarly situated California consumers, and the general public, seeks restitution of all money they paid for Defendant's illegally sold Product, an injunction prohibiting Defendant from continuing to sell the Product with the false representations set forth above, corrective advertising and all other relief this Court deems appropriate, consistent with Business & Professions Code §17203.

COUNT II

Violations of the Consumers Legal Remedies Act – Civil Code §1750 *et seq.*

(On Behalf of the Multi-State or California-Only Class)

94. Plaintiff Gershman repeats and re-alleges the allegations contained in the paragraphs above, as if fully set forth herein.

95. Plaintiff Gershman brings this claim individually and on behalf of the

Class.

96. This cause of action is brought pursuant to the Consumers Legal Remedies Act, California Civil Code §1750, et seq. (the "Act"). Similar statutes, identical in their material respects, are in effect in all states that are a part of the alleged Multi–State Class.

97. Plaintiff Gershman is a consumer as defined by California Civil Code §1761(d). Defendant's Flintstones Healthy Brain Support is a "good" within the meaning of the Act.

98. Defendant violated and continues to violate the Act by engaging in the following practices proscribed by California Civil Code §1770(a) in transactions with Plaintiff Gershman and the Class which were intended to result in, and did result in, the sale of Flintstones Healthy Brain Support:

> (5) Representing that [Flintstones Healthy Brain Support has] . . . approval, characteristics, . . . uses [and] benefits . . . which [it does] not have . . . .
>
> * * *
>
> (7) Representing that [Flintstones Healthy Brain Support is] of a particular standard, quality or grade . . . if [it is] of another.
>
> * * *
>
> (9) Advertising goods . . . with intent not to sell them as advertised.
>
> * * *
>
> (16) Representing that [Flintstones Healthy Brain Support has] been supplied in accordance with a previous representation when [it has] not.

99. Defendant violated the Act by misrepresenting material facts on the Flintstones Healthy Brain Support labeling and packaging and associated advertising, as described above, when the representations were false and misleading.

100. As alleged herein, Plaintiff has suffered injury in fact and lost money or property as a result of Defendant's conduct because she purchased Flintstones

Healthy Brain Support in reliance on Defendant's false representations.

101. Plaintiff and other members of the Class have in fact been deceived as a result of their reliance on Defendant's material false representations described above. This reliance has caused harm to Plaintiff and other members of the Class who each purchased Flintstones Healthy Brain Support. Plaintiff and the other Class members have suffered injury in fact and lost money as a result of these deceptive and fraudulent practices.

102. Pursuant to California Civil Code §1782(d), Plaintiff Gershman and the Class seek a Court order enjoining the above-described wrongful acts and practices of Defendant and for restitution and disgorgement.

103. Pursuant to §1782 of the Act, Plaintiff Gershman notified Defendant in writing by certified mail of the particular violations of §1770 of the Act and demanded that Defendant rectify the problems associated with the actions detailed above and give notice to all affected consumers of Defendant's intent to so act. A copy of the letter is attached hereto as Exhibit B.

104. If Defendant fails to rectify or agree to rectify the problems associated with the actions detailed above and give notice to all affected consumers within 30 days of the date of written notice pursuant to §1782 of the Act, Plaintiff Gershman will amend this Complaint to add claims for actual, punitive and statutory damages, as appropriate.

105. Pursuant to §1780(d) of the Act, attached hereto as Exhibit C is the affidavit showing that this action has been commenced in the proper forum.

PRAYER FOR RELIEF

Wherefore, Plaintiff prays for a judgment:

A. Certifying the Class as requested herein;

B. Awarding restitution and disgorgement of Defendant's revenues to Plaintiff and the proposed Class members;

C. Awarding injunctive relief as permitted by law or equity, including: enjoining Defendant in California from continuing the unlawful practices as set forth herein;

D. Ordering Defendant to engage in a corrective advertising campaign;

E. Awarding attorneys' fees and costs; and

F. Providing such further relief as may be just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial of her claims by jury to the extent authorized by law.

Dated: December 4, 2014

BONNETT, FAIRBOURN, FRIEDMAN & BALINT, P.C.

s/*Patricia N. Syverson*
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