

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS**

SEAN PORTER, On Behalf of Himself
and All Others Similarly Situated,

Plaintiff,

v.

BAYER HEALTHCARE, LLC, a
Delaware Limited Liability Company,

Defendant.

Case No.:

CLASS ACTION COMPLAINT

Plaintiff Sean Porter brings this action on behalf of himself 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”)¹. The Product is not a multivitamin. The Product’s sole represented benefit is to support brain function. 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 taking the Product will “Support[] Healthy Brain Function”. On each and every package, where it cannot be missed by consumers, is the Product name – “Flintstones Supplements”. And, immediately under the Product name it states “Healthy”. And, in far larger print under that it states “BRAIN SUPPORT”. Under all this is the prominent representation “Omega-3 DHA Supports Healthy Brain Function” (collectively, “the brain function representations”).

3. The best evidence to judge whether algal DHA provides any brain function benefits are randomized controlled trials (“RCTS”). Five RCTs involving the *same* algal

¹ “Life’s DHA” – is a highly processed fermented algae Omega-3 DHA.

DHA as is in the Product have found no causative link between DHA algal oil supplementation and brain support/function. The RCTs found that algal DHA does not support brain function even though they were funded by the manufacturer of the Life's DHA in the Product and used 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).

4. In addition to not supporting healthy brain function, the algal oil derived DHA in the Product is superfluous. American children and adults, who are the target market for the Product, consume adequate amounts of DHA derived from dietary sources such as fish, soybean oil, canola oil, green leafy vegetables and flax seeds.

5. 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.

6. 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.

7. Even if there were DHA deficient children and adults in the United States – which there are not – they would derive no brain health benefit from the Product because only a trivial amount of DHA in the Product enters the brain after it is consumed. The brain contains about 5000 mg of DHA, a serving 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, in the first day with less entering in each subsequent day. This amount is so trivial that it cannot and does not support the brain or its functioning in any manner.

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

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

10. As a result of Bayer's deceptive brain function 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 benefits because it is the only stated benefit of the Product.

11. Plaintiff brings this action on behalf of himself and other similarly situated consumers who have purchased Flintstones Healthy Brain Support to halt the dissemination of this false, misleading and deceptive advertising message, 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.

JURISDICTION AND VENUE

12. 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.

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

14. Venue is proper in this Court pursuant to 28 U.S.C. §§1391(a) and (b) because a substantial part of the events giving rise to Plaintiff's claims occurred while he resided in this judicial district. Venue is also proper under 18 U.S.C. §1965(a) because Defendant transacts substantial business in this District.

PARTIES

15. Plaintiff Sean Porter is a citizen of Illinois and resides in Roselle, Illinois. In or around the July 2014, Plaintiff purchased one bottle of Flintstones Healthy Brain Support from Walgreens in Roselle, Illinois. Prior to purchasing the Product, Plaintiff was exposed to and saw Bayer's brain function representations by reading the Product's label. Plaintiff purchased the Product in reliance on Bayer's brain function representations. The Product Plaintiff purchased does not support healthy brain function as represented. As a result, Plaintiff suffered injury in fact and lost money. Had Plaintiff known the truth about Bayer's misrepresentations, he would not have purchased the Product.

16. Defendant Bayer Healthcare, LLC is a Delaware limited liability company with its principal place of business in Whippany, New Jersey. At all relevant times, Defendant manufactured, distributed, marketed and sold the Product and created the deceptive brain function representations, which it caused to be disseminated to consumers throughout the United States, including Illinois.

FACTUAL ALLEGATIONS

Flintstones Healthy Brain Support

17. Since at least August 2013, Bayer has manufactured, distributed, marketed

and sold the Product throughout the United States, including Illinois. The Product is marketed as a supplement with the singular purpose of supporting healthy brain function. 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).

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

19. Each and every consumer who purchases the Product is exposed to Bayer's deceptive brain function representations, which are the only represented Product benefit and appear prominently and conspicuously on the front of the Product's packaging, as well as in the Product name – "Flintstones Healthy Brain Support" as follows:



Flintstones Healthy Brain Support Does Not Support Healthy Brain Function

20. 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 an immature short-chain omega-3 fatty acid made from an extract of mutated and fermented algae. Contrary to Bayer's representations made on each and every Product package, DHA algal oil does not support healthy brain function.

21. Several RCTs, regarded by experts in the field as the "gold standard" of scientific evidence, and the only credible means of proving whether a substance has an effect in humans, have found no brain function benefits from consumption of supplemental DHA even in much higher dosages than in a serving of the Product.

22. 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. 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).

23. In a 2008 RCT, Johnson and colleagues divided the subjects into 4 groups. Over 20 memory and processing tests were conducted and scored after 16 weeks of DHA supplementation at 800 mg per day. DHA was found to be beneficial in 1 test on verbal fluency and no better than placebo on over 20 others. Because the authors defined statistical significance as $p < 0.05$, by chance alone 1 out of 20 measures was expected to be statistically different. Thus, because Johnson made 25 measures with the DHA group, the 1 positive finding is due to chance and the 24 comparisons that were no better than placebo show that 800mg per day of DHA does not provide brain health benefits. See Johnson EJ, et al., *Cognitive Findings Of An Exploratory Trial Of Docosahexaenoic Acid And Lutein Supplementation In Older Women*, 11 Nutr. Neurosci. 75-8 (2008).

24. In a 2009 RCT, David Kennedy and colleagues examined the effects of 400 or 1000 mg 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, both the one positive and the one negative finding are due to chance but the 33 that showed no effect by their sheer weight are not due to chance and demonstrate a lack of efficacy. *Id.* In fact, the authors conclude: “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.*

25. 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 mg DHA per day compared to placebo on attention scores in healthy boys. For the 4 endpoints that were registered with clinicaltrial.gov,² McNamara and colleagues reported no effects of DHA on all 4 measures.

26. Finally, in a 2012 RCT, Alexandra Richardson and colleagues examined placebo or 600 mg 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). To the extent that Richardson and colleagues represents the general population, at the end of the study, Richardson and colleagues reports 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.

27. All of the RCTs using the DHA in the Product showed no benefit on the primary registered endpoints—the only endpoints from which cause and effect conclusions can be drawn. Each of the studies had adequate sample sizes, were typical of the size commonly used in and relied upon in the scientific community and were adequate to test the hypotheses presented in each study. Additionally, the RCTs used much higher doses of DHA than that found in the Product – at least eight times the amount of DHA in the recommended dosage for children 2-3 years old and 4 times the amount in the recommended dosage for adults and children 4 years and older – making it even more likely that a positive result would be found, yet there were none that could not be attributed to

² Every clinical trial is required to register its study with clinicaltrial.gov, setting 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.

chance alone.

28. 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 cognitive development. Bayer's brain function representations are false and misleading and reasonably likely to deceive the consumer.

29. Furthermore, American children and adults get sufficient DHA in their daily diet. *Molecular* DHA does play a role in the brain. But, 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 foods containing oxygen; nor do humans need DHA supplementation. In fact, there is only one reported case of DHA deficiency in the United States in the last thirty or so years and it involved a girl on an intravenous diet.

30. 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 by eating fish, soybean oil, canola oil, green leafy vegetables and flax seeds among other vegetables. 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 as it is not an essential nutrient and American adults and children are already consuming adequate amounts of its precursor ALA.

31. And, 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.³ 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.

32. Even if the algal oil derived DHA was not superfluous, such a trivial amount of the DHA in a serving of Product enters the brain that it is incapable of providing any brain function 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, approximately 0.0005% of an oral dosage of 50 mg of DHA enters the brain in 24 hours with much less entering in each subsequent day. And, because the brain contains about 5000 mg of DHA, a serving 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, in the first day. Even at the highest point in the range of DHA in the Product, this amount of DHA is trivial and does not contribute to brain function. Indeed, RCTs have found that DHA in much higher dosages does not provide brain health benefits.

33. Thus, the overwhelming weight of scientific evidence is that DHA supplementation does not support healthy brain function in U.S. consumers aged 2 and older.

The Impact of Bayer's Wrongful Conduct

34. 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 "Supports Healthy Brain Function" in children ages 2 and older, as well as adults.

35. Plaintiff and Class members have been and will continue to be deceived or

³ 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.

misled by Bayer's deceptive brain function representations. Plaintiff purchased the Product during the relevant time period and in doing so, read and considered the Product label and based his decision to buy the Product on the brain function representations. Bayer's brain function representations were a material factor in influencing Plaintiff's decision to purchase the Product. Plaintiff would not have purchased the Product had he known that Bayer's brain function representations were false and misleading.

36. 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, supported healthy brain function, when, in fact, it does not.

37. Bayer, by contrast, reaped enormous profits from its false marketing and sale of the Product.

CLASS DEFINITION AND ALLEGATIONS

38. Pursuant to Rule 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure, Plaintiff seeks to represent a Multi-State class defined as all consumers in Illinois and states with similar state consumer protection laws⁴ who purchased Flintstones Healthy Brain Support (the "Class"). 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.

39. In the alternative, pursuant to Rule 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure, Plaintiff seeks to represent all Class members who purchased Flintstones Healthy Brain Support in Illinois. Excluded from this Class are Defendant and

⁴ While discovery may alter the following, Plaintiff preliminarily alleges that Bayer violated the laws prohibiting unfair and deceptive trade practices of the states and territories wherein Class members reside, including: Cal. Bus. & Prof. Code §17200 et seq.; California Civil Code §1750 et seq.; 815 Ill. Comp. Stat. 502/1, et seq.; Mass. Gen. Laws ch.93A et seq.; Mich. Stat. §445.901 et seq.; Minn. Stat. §8.31 et seq.; Missouri Stat. §407.010 et seq.; N.Y. Gen. Bus. Law § 349, et seq.; and Wash. Rev. Code. §19.86.010 et seq.

its officers, directors and employees and those who purchased Flintstones Healthy Brain Support for the purpose of resale.

40. **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.

41. **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 true, or are misleading, or objectively reasonably 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.

42. **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 representations that accompanied each and every bottle of Flintstones Healthy Brain Support. Plaintiff is advancing the same claims and legal theories on behalf of himself and all members of the Class.

43. ***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.

44. ***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.

45. 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.

46. Unless a Class is certified, Bayer will retain monies received as a result of its conduct that were taken from Plaintiff and Class members. 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.

47. 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 Illinois Consumer Fraud Act
(On Behalf of the Multi-State or Alternatively, Illinois-Only Class)

48. Plaintiff re-alleges and incorporates by reference the allegations contained in the paragraphs above as if fully set forth herein.

49. In Illinois, the “Consumer Fraud and Deceptive Business Practices Act” 815 Ill. Comp. Stat. 502/1, et seq. (“the Act”), like the consumer fraud acts of numerous other states across the nation, prohibits deceptive acts and practices in the sale of such products as Bayer’s Flintstones Healthy Brain Support.

50. Plaintiff and the Class were injured by Bayer’s deceptive misrepresentations, and these misrepresentations were material and deceived Plaintiff and the Class.

51. Bayer does business in Illinois, sells and distributes the Product in Illinois, and engaged in deceptive acts and practices in connection with the sale of the Product in Illinois and elsewhere in the United States.

52. The Product purchased by Plaintiff and the Class was a “consumer item” as that term is defined under the Act.

53. Bayer misrepresented material information known to Bayer as set forth above concerning the Product, which has caused damage and injury to Plaintiff and the Class.

54. Bayer’s deceptive acts occurred in a course of conduct involving trade and commerce in Illinois and throughout the United States.

55. Bayer’s deceptive acts proximately caused actual injury and damage to Plaintiff and the Class.

56. Bayer intended Plaintiff and all Class members to rely on its deceptive acts.

57. The conduct of Bayer constituted a consumer fraud under the Illinois Consumer Fraud Act and similar laws in other states.

WHEREFORE, Plaintiff and the Class pray as follows:

- A. That the Court enter an order certifying this action as a class action – either as a multi-state class or, in the alternative, as an Illinois class;
- B. That the Court enter an Order against Bayer awarding to Plaintiff and the Class compensatory/actual damages and such other monetary relief as the Court deems appropriate;
- C. That the Court enter an order granting declaratory and injunctive relief as permitted by law or equity, including enjoining Bayer from continuing the unlawful practices as set forth herein;
- D. Attorneys’ fees, expert fees and costs; and
- E. Such other and further relief as the Court deems just and proper.

Dated: October 14, 2014

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