THIGPEN LEGAL, P.C.
Jordanna Thigpen (SBN 232642)
9595 Wilshire Boulevard, Ste. 961
Beverly Hills, CA 90212
T: (310) 210-7491
F: (310) 362-0456
Email: jt@thigpenlegal.com

HART MCLAUGHLIN & ELDRIDGE
Steven A. Hart, Partner (to be admitted *pro hac vice*)
Stewart M. Weltman, Of Counsel (to be admitted *pro hac vice*)
One South Dearborn, Suite 1400
Chicago, Illinois 60603
T: (312) 955-0545
Email: sweltman@hmelegal.com; shart@hmelegal.com

Additional Counsel Listed on Signature Page

IN THE UNITED STATES DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA

RICHARD POOLE, on behalf of himself and all others similarly situated,

Plaintiff,

v.

QUINCY BIOSCIENCE HOLDING COMPANY, INC., a Wisconsin corporation; QUINCY BIOSCIENCE, LLC, a Wisconsin limited liability company; PREVAGEN, INC., a Wisconsin corporation, d/b/a SUGAR RIVER SUPPLEMENTS; QUINCY BIOSCIENCE MANUFACTURING, LLC, a Wisconsin limited liability company; MARK UNDERWOOD, individually and as an officer of QUINCY BIOSCIENCE HOLDING COMPANY, INC., QUINCY BIOSCIENCE, LLC, and PREVAGEN INC.; MICHAEL BEAMAN, individually and as an officer of QUINCY BIOSCIENCE HOLDING COMPANY, INC., QUINCY BIOSCIENCE, LLC, and PREVAGEN INC.,

Defendants.

COMPLAINT FOR DAMAGES AND RESTITUTION

CLASS ACTION

DEMAND FOR JURY TRIAL

Plaintiff RICHARD POOLE brings this action on behalf of himself and all others similarly situated against Defendants QUINCY BIOSCIENCE HOLDING COMPANY, INC., a corporation; QUINCY BIOSCIENCE, LLC, a limited liability company; PREVAGEN, INC., a corporation, d/b/a SUGAR RIVER SUPPLEMENTS; QUINCY BIOSCIENCE MANUFACTURING, LLC, a limited liability company; MARK UNDERWOOD, individually and as an officer of QUINCY BIOSCIENCE HOLDING COMPANY, INC., QUINCY BIOSCIENCE, LLC, and PREVAGEN INC.; MICHAEL BEAMAN, individually and as an officer of QUINCY BIOSCIENCE HOLDING COMPANY, INC., QUINCY BIOSCIENCE, LLC, and PREVAGEN INC. (together, "Defendants") and alleges upon personal knowledge as to his own acts and experiences and, as to all other matters, upon information and belief:

FACTUAL ALLEGATIONS

Prevagen

1. Surveys show that people over 50 are more fearful of memory loss/Alzheimer's/dementia than they are of cancer.

2. Since at least the fall of 2007, Defendants have manufactured, distributed, marketed, and sold a purported brain health supplement: Prevagen. The "Prevagen Products" are currently marketed as a dietary supplement that purportedly provides a variety of brain health and brain function claims such as providing "healthy brain function", "memory improvement," "sharper mind" and "clearer thinking"[1].

3. And while the package labeling may have changed over the years the same consistent message is made – take Prevagen and you will get

[1] *See, e.g.*, https://prevagen.com/; https://prevagen.com/collections/brain-health-memory-improvement-supplements (last visited February 26, 2024).

the above-represented brain health benefits.

4. Defendants have also engaged in widespread nationwide marketing campaigns over the television networks – in fact, it's hard to avoid seeing a television ad for Prevagen when you watch any of the major cable networks.

5. The television ads convey the same messages, with mostly older people endorsing the product in the advertisements.

6. For instance, one of these ads is about a person named "Douglas" who was paid to make his testimonial and who claimed that he was over 65 and from Chicago, Illinois. In the ad he claims that he is surrounded by younger people in his work as a writer. He then states that he "had to get help somewhere along the line to stay competitive" and "I started taking Prevagen and overtime my memory improved – it was a game changer for me."[2]

7. The sole active ingredient that is represented by Defendants as providing these brain health benefits is a synthetically-made dietary protein called apoaequorin.

8. In its natural state, apoaequorin is found in certain jellyfish and is the matter that causes these jellyfish to illuminate.

9. The synthetic apoaequorin manufactured and sold by Defendants does not illuminate.

10. Knowing full well that Prevagen does not and cannot provide brain health benefits, and as noted below, having admitted as such to the FDA in 2016, Defendants through their uniform marketing messages on their labeling, on television and on their website (https://prevagen.com) induce consumers albeit mostly elderly persons – and many on fixed

[2] *See, e.g.*, https://www.youtube.com/watch?v=-MNWQGbXA2A.

income – to pay approximately $60 a month for a product that is worthless.

Defendants' Search for an Angle to Market Inexpensively Made Synthetic Apoaequorin

11. The purported connection between Defendants' synthetic apoaequorin and brain health is the byproduct of a scientific misnomer that came to its creator, Defendant Mark Underwood, in what he claims was an epiphany.

12. In fact, how Underwood and Quincy arrived at apoaequorin as a supplement that purportedly provides brain health benefits is a tortured tale that itself demonstrates that Underwood and Quincy merely searched for a use for cheaply made synthetic apoaequorin so that they could make millions off of unsuspecting consumers.

13. Defendant Underwood authored a book in 2007 entitled "Gift From the Sea" in which he details how he supposedly "discovered" apoaequorin's purported brain health benefits.

14. The story told by Underwood purports to start when, as an undergrad at the University of Wisconsin Milwaukee, he somehow became intrigued with whether apoaequorin "might protect brain cells and through that process, guard against neurodegenerative conditions like Alzheimer's, Parkinson's and stroke." *See* Mark Y. Underwood, *Gift From the Sea* (AuthorHouse 2007), attached as **Exhibit 1A**.

15. Thus, Underwood writes, he began recording copious notes about his "vision" of "using jellyfish protein to slow down memory loss and aging, an idea that seemed too good to be true…." *Id.* And it was – for Underwood and his co-Defendants but not for consumers.

16. According to Underwood, "I took that interest to the next level after reading a case study[3] about a patient who contracted the symptoms of

[3] Even though this case study had nothing to do with brain health, it should be noted

Guillain-Barre Syndrome after a jellyfish sting and was successfully treated with calcium channel blockers." *See* Underwood, attached as **Exhibit 1B**.[4]

17. According to Underwood it was less significant to him that the person's Guillain-Barre symptoms improved to "some extent" because what "fascinated" him was that "jellyfish could inflect his problem, yet not suffer from it within its own simple nervous system." *Id*. [5]

18. From this he supposedly had many questions: (1) "What is calcium's role in damaging the nervous system?" (2) Can mediating calcium fight neurological conditions? (3) How can jellyfish deliver a sting and not suffer any neuropathy? [and most important] (4) "Why doesn't a jellyfish poison itself?" Underwood, attached as **Exhibits 1B and 1C.**

19. Intriguing questions – but reflecting a lack of basic knowledge such as that: (1) Calcium's role and its levels, at least in the brain, are tightly controlled (*e.g.* mediated) by the brain itself to help maintain the nervous system – as too much calcium can be just as bad as too little.

20. What connection any of Underwood's opinions had to apoaequorin is opaque at best and actually pure fantasy as far as real science is concerned.

21. For instance, his logic about the benefits of supplemental

---

that case studies about a single individual is a type of clinical evidence that cannot be relied upon to reach any conclusions about the efficacy of the substance being tested – e.g. in this case channel blockers to treat a jellyfish sting. *See* Patricia B. Burns *et al*., *The Levels of Evidence and their Role in Evidence Based Medicine*, 128 Plast. Reconstr. Surg. 305, 305-310 (2011), attached hereto as **Exhibit 2**.

[4] Calcium channel blockers are used to lower blood pressure by preventing calcium from entering the cells of the heart and arteries – they have nothing to do with brain health. *Calcium Channel Blockers*, Mayo Clinic (Aug. 23, 2023), attached hereto as **Exhibit 3**.

[5] Of course, there is nothing unique or fascinating about this, as numerous venomous animals, plants, and the like do not suffer from their own poisons.

calcium-binding proteins was as simplistic as it was wrong. As Underwood saw it, "after all, it had long been documented in the medical community that the depletion of calcium-binding proteins was associated with aging and the onset of neurological diseases. Why not just add these valuable proteins back into the body [via apoaequorin]." *See* **Exhibit 1A**.

22. But again, it needs to be repeated – the brain tightly controls the levels of calcium because too much can be as bad as too little. So even if Prevagen did add these "valuable proteins" into the body, which it does not, more is not better when it comes to calcium and the brain.

23. Nevertheless, Underwood relates yet another most convenient event – Underwood met a molecular biologist during a volleyball game and mentioned that he was interested in studying jellyfish proteins. Loand behold this person said he too was intrigued with apoaequorin and better yet he knew how to make it in a lab. *See* **Exhibit 1D,** attached hereto.

24. As Underwood exclaimed in his book, "What were the odds that I would meet, during a volleyball game, one of the few people in the world who knows how to make this remarkable protein?" *Id.*

25. Of course, there is nothing remarkable about how synthetic apoaequorin is made – as set forth in Quincy's GRAS (Generally Regarded as Safe) document submitted to the FDA in 2016, in response to a warning letter issued by the FDA to Defendants, synthetic apoaequorin is "a standardized protein preparation produced by microorganism recombinant technology" – a technology that has been used since the 1970s to produce various recombinant proteins.

26. But there was even more serendipity to Underwood's fishy tale. Underwood writes that he then met with Defendant Beaman, who as it just turned out, was interested in diversifying his investments so: "That day we sketched out a business plan on a lunch napkin for a new company called

Quincy Bioscience. Our goal? To take this jellyfish protein and create a *drug* to help fight Alzheimer's disease and other related neurodegenerative conditions." *See* **Exhibit 1E**, attached hereto.

27. And that's how Underwood, Beaman and Quincy first marketed Prevagen – not as a dietary supplement to help support brain health and function – but as a *drug* to treat diseases like Alzheimer's and other similar conditions.

28. Apparently, Underwood and Beaman did not know that the FDA considers claims about Alzheimer's and other dementias as disease claims, requiring that the claims they were making about Prevagen be subject to the FDA's new drug approval process ("NDA").

29. But they learned later on when, as discussed below, the FDA issued Quincy a warning letter in 2012 about its marketing Prevagen as a drug without prior FDA approval.

30. Admittedly, the human brain's neurons (the cells in our brains that govern its functions) do require calcium-binding proteins to perform their functions.

31. But, as opposed to Underwood's unscientific notions of the brain and its health as reflected in his book and in Defendants' marketing and sale of Prevagen, the brain does not need nor would it accept help from the outside, such as synthetic apoaequorin, as the brain endogenously makes its own calcium-binding proteins.

32. In fact, apoaequorin is not one of the calcium-binding proteins that are made by the brain, so it's hard to fathom, how apoaequorin would be used by the human brain even if it ever got in, particularly since after millions of years of evolution, what the brain needs and what it uses have been carefully developed through evolution and, as a result, what gets into the brain is tightly regulated and controlled by something called the blood-

brain-barrier ("BBB").

33. It is true that, as we age, like everything else in our bodies, the brain's ability to make calcium-binding proteins slow down.

34. But this does not mean that, as a result, the brain requires more calcium-binding proteins from outside the brain.

35. That is because, the regulation of the levels of calcium-binding proteins and thus calcium in the brain is tightly and continuously controlled by the brain itself to maintain proper levels as needed in its various areas – as sometimes areas in the brain require more calcium but at other times they require less calcium.

36. In this sense, calcium is not a more-is-better substance when it comes to the brain and any purported interference from the outside, such as the introduction of apoaequorin into the brain in any material amount would pose a risk of upsetting that balance, and since it would be foreign to the brain, could likely cause an immune response/reaction in the brain that could be deleterious.

37. And as discussed below, that is one of the many reasons why if a molecule of intact apoaequorin survived digestion (which as set forth below is not possible) and arrived at the brain, it would not be allowed to enter.

38. Yet, the sole scientific premise upon which Defendants have built their claims that Prevagen provides its supposed brain health benefits is that Prevagen supposedly provides more calcium-binding proteins to the brain. In fact, in the 2016 published version of a highly flawed clinical study called the Madison Memory Study ("MMS") Underwood and his co-authors asserted, without any reliable scientific support, that apoaequorin works by regulating the levels of calcium in the brain. *See* Daniel L. Moran, Mark Y. Underwood, Taylor A. Gabourie & Kenneth C. Lerner, *Effects of a*

Supplement Containing Apoaequorin on Verbal Learning in Older Adults in the Community, 30 Advances in Mind-Body Medicine 1 (2016), attached hereto as **Exhibit 4**.

39. Moreover, as will be seen below, Underwood and Quincy's crude and unscientific illogic about why Prevagen and its so-called unique calcium-binding protein might work, ignores such things as that: (a) once Prevagen hits the stomach it is no longer a calcium-binding protein, as it is protilized by the first of a torrent of enzymes in the stomach and then is assaulted in the intestines by a battalion of digestive enzymes, such that by the end of the digestion process, it is completely digested/hydrolyzed into common amino acids like all other dietary proteins; (b) even then the amount of calcium that would be bound by an undigested 10 mg dose of Prevagen is negligible (about 10,000 times less than our daily requirements); and (c) if for some reason a molecule of apoaequorin survived digestion and somehow arrived outside the brain, it would be prevented from entering the brain because the BBB blocks molecules with masses over 0.4-06 kilodaltons or that are hydrophilic (soluble in water) – and apoaequorin has a mass of approximately 22 kilodaltons and is highly soluble in water. So Prevagen's apoaequorin just cannot enter nor affect the brain in the manner that Defendants represent.

40. In fact, the BBB and its impermeability is one of the primary reasons why treatments for such ailments as brain cancer or Alzheimer's have failed and scientists have been struggling for decades searching for the means of getting these treatments – drugs that might actually work – to the brain for the treatment of diseases.

The FDA Steps In and Issues Warning Letters

41. But the actual science did not deter Defendants. At the beginning of the promotion of Prevagen, starting in 2007, Mr. Underwood

and Quincy made a series of outlandish claims about Prevagen that involved its treating dementia, Parkinson's disease, and other neurological conditions.

42. These claims were made without an iota of clinical research on Prevagen and its purported treatment of human diseases, and instead were claimed by Underwood and others promoting Prevagen based upon the speculative claim that apoaequorin regulated calcium levels in the human brain.

43. As noted above, such claims were actually illegal disease claims that amounted to Prevagen being sold as a drug without ever gaining drug approval from the FDA. In 2012, the FDA caught up with Defendants. And while Plaintiff's claims here are not based upon Defendants' violations of FDA law by selling Prevagen as an unapproved drug, this background provides evidence as to how Prevagen eventually ended up being sold as a dietary supplement, devoid of any reliable scientific support and overwhelming science demonstrating why it could never provide such benefits.

44. Defendants' illegal marketing of Prevagen, as an unapproved drug, was raised in an October 16, 2012, warning letter from the FDA. *See* October 16, 2012 Warning Letter from Michael Dutcher, FDA Director, to Mark Underwood, President, Quincy Bioscience Manufacturing Inc., attached hereto as **Exhibit 5**.

45. Thus, began a series of communications with the FDA and Defendants discussed in further detail below, which ultimately resulted in the Defendants admitting that once digested, Prevagen is no longer a calcium-binding protein but, instead, is completely digested into common amino acids like other dietary proteins – or to put it in simple terms – Prevagen has no more direct effect on brain health than a very minute piece

of baloney or any dietary protein.

46. This warning letter process also caused Defendants to shift their marketing claims to Prevagen as a dietary supplement, so they would hopefully avoid FDA's warnings about Defendants making illegal disease claims.

47. But the fact is that the story of Prevagen has always been about the Defendants trying to find a claim for a product that costs pennies to make but that could make them millions, while avoiding FDA scrutiny.

48. And the easiest route was to market Prevagen as a dietary supplement, as the federal dietary supplement laws do not require a dietary supplement manufacturer to submit the scientific evidence to support their labeling claims, but instead merely requires the supplement manufacturer to submit a letter before they begin selling the product that vouches that they have the required scientific support for their labeling claims.

The False and Deceptive Marketing of Prevagen as a Dietary Supplement

49. Today, Prevagen is sold in virtually every major food, drug, and mass retail outlet in the country as well as online, where consumers can sign up to receive their Prevagen directly from Defendants every month. *See* https://prevagen.com.

50. If a consumer purchases online, here are just some of the false and misleading claims made on the website's first page:[6]

(a) "Prevagen is an over-the-counter supplement for healthy brain function and memory improvement citing to the MMS a wholly unreliable and scientifically unsound study;

(b) Prevagen "uniquely supports brain function"

(c) "Prevagen has been clinically shown to safely and effectively improve memory" (again referring to the MMS

[6] https://prevagen.com/ (last visited February 26, 2024).

and attaching an unpublished version of one of the various versions of the MMS study that Defendants drafted over time to support their false marketing claims).

51. The website then offers up links to short blurbs containing various individual testimonials about Prevagen and if one then links to their videos, are the bottom left-hand corner, of the video, for a total of 4 seconds of a 90 second video, it states that these are paid endorsers – in short "Paid Testimonialists" for Defendants.

52. And yet again, despite the FDA's warnings, when one clicks to a link Defendants provide regarding the purported safety of Prevagen, among the articles cited by Defendants is one that still concerns disease related claims about Prevagen "A brief review of three common supplements used in Alzheimer's Disease"[7]; and (2) one involves a study in rats (an albeit horribly conducted study) that deals with whether Prevagen protects brain cells from injury in a simulated ischemic stroke.

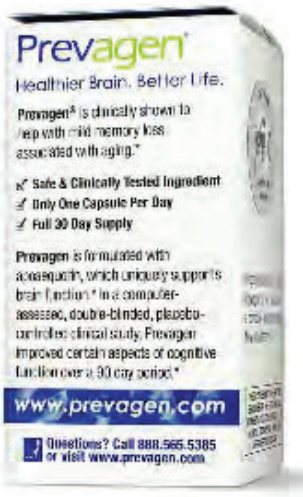
53. And if one clicks on the "shop" link one sees pictures of the front labels of each Prevagen product[8] – all of which make the same uniform representations (summarized herein) on their front panels (the only differences between these products is their dosing and whether one chooses

[7] Although not a basis upon which Plaintiff relies to support his claims this is a direct violation of FDA's proscription that supplement manufacturers cannot and should not refer to articles discussing the treatment of diseases in reference to their products. *See* FDA Act, 21 U.S.C. section 403(r)(1)(B); *see also* 21 C.F.R. section 101.14(a)(1) (2000) ("Implied health claims include those statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition"), and FDA Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 65 Fed. Reg. 1021 at Section H (proposed January 6, 2000) (codified at 21 C.F.R. part 101).

[8] Only two are not part of this case – Prevagen Professional and Prevagen NeuroShake.

capsules or chewable). A screenshot of the labeling of each Prevagen product that is a focus of this case is set forth below. As is readily seen, other than differences in dosing[9], the same labeling claims are made on every Prevagen product.

54. These label panels set forth below are representatives of any and all labels used during the class period, as if minor changes were made, the same false and misleading representatives were made by Defendants:

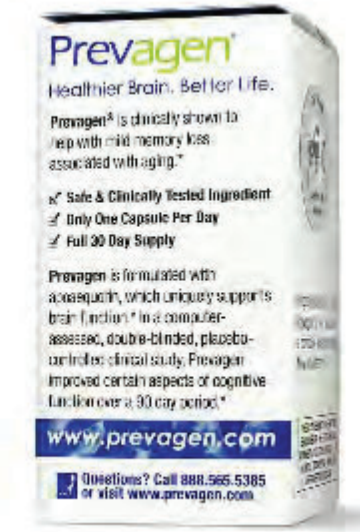


[9] The "extra strength" dose is double the six of the regular strength products but, as alleged above, doubling the dose of apoaequorin does not improve the strength of the extra strength products as Prevagen, as any dose sold is worthless and incapable of providing any of the brain health benefits Defendants represent.


Clinically Tested Ingredient
Prevagen
Improves Memory
REGULAR STRENGTH
SUPPORTS:
Healthy Brain Function*
Sharper Mind*
Clearer Thinking*
ONE CAPSULE DAILY
Dietary Supplement
30 Capsules


Supplement Facts
Serving Size: 1 capsule
Amount per capsule
% Daily Value
Vitamin D (as D3 cholecalciferol) 50 mcg 250%
Apoaequorin 10 mg †
† Daily Value not established.
Other ingredients: microcrystalline cellulose, vegetable capsule (cellulose, water), maltodextrin, contains 2% or less of: casein peptones, lactose, magnesium stearate (vegetable source), modified corn starch, salt, soy peptones, sugar.
Contains: Milk and Soy
Contains a bioengineered food ingredient.
Distributed by: Quincy Bioscience Holding Company, Inc., Madison, WI 53717, USA
Suggested use: Take one capsule daily in the morning, with or without food.


Originally discovered in jellyfish, Prevagen® is now produced in a controlled scientific process. Now with Vitamin D.
*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.


Prevagen
Healthier Brain. Better Life.
Prevagen® is clinically shown to help with mild memory loss associated with aging.*
Safe & Clinically Tested Ingredient
Only One Capsule Per Day
Full 30 Day Supply
Prevagen is formulated with apoaequorin, which uniquely supports brain function.* In a computer-assessed, double-blinded, placebo-controlled clinical study, Prevagen improved certain aspects of cognitive function over a 90 day period.*
www.prevagen.com
Questions? Call 888.565.5385 or visit www.prevagen.com


60 Day Supply
Prevagen
Improves Memory
EXTRA STRENGTH
SUPPORTS:
Healthy Brain Function*
Sharper Mind*
Clearer Thinking*
ONE CAPSULE DAILY
Dietary Supplement
60 Capsules


Supplement Facts
Serving Size: 1 capsule
Amount per capsule
% Daily Value
Vitamin D (as D3 cholecalciferol) 50 mcg 250%
Apoaequorin 20 mg †
† Daily Value not established.
Other ingredients: microcrystalline cellulose, vegetable capsule (cellulose, water), maltodextrin, contains 2% or less of: casein peptones, lactose, magnesium stearate (vegetable source), modified corn starch, salt, soy peptones, sugar.
Contains: Milk and Soy
Contains a bioengineered food ingredient.
Distributed by: Quincy Bioscience Holding Company, Inc. Madison, WI 53717, USA
Suggested use: Take one capsule daily in the morning, with or without food


6459
electronically protected
Originally discovered in jellyfish, Prevagen® is now produced in a controlled scientific process. Now with Vitamin D.
*Based on a clinical study of subgroups of individuals who were cognitively normal or mildly impaired.
*THESE STATEMENTS HAVE NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE OR PREVENT ANY DISEASE.


Prevagen
EXTRA STRENGTH
Healthier Brain. Better Life.
Prevagen® Extra Strength is designed to have twice the apoaequorin as Prevagen Regular Strength.
Safe & Clinically Tested Ingredient
Only One Capsule Per Day
Full 60 Day Supply
Prevagen Extra Strength is formulated with apoaequorin, which uniquely supports brain function.* In a computer-assessed, double-blinded, placebo-controlled clinical study, Prevagen improved certain aspects of cognitive function over a 90 day period.*
www.prevagen.com
Questions? Call 888.565.5385 or visit www.prevagen.com


Clinically Tested Ingredient
Prevagen
Improves Memory
CHEWABLES
Mixed Berry Flavor
SUPPORTS:
Healthy Brain Function*
Sharper Mind*
Clearer Thinking*
ONE TABLET DAILY
Dietary Supplement
30 Tablets


Supplement Facts
Serving Size: 1 tablet
Amount per tablet
% Daily Value
Total Carbohydrate 1 g <1%**
Vitamin D (as D3 cholecalciferol) 50 mcg 250%
Apoaequorin 10 mg †
** Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established
Other ingredients: Sorbitol, mannitol, natural flavors, contains 2% or less of: beet juice powder (for color), casein peptones, acesulfame potassium, magnesium stearate (vegetable source), maltodextrin, modified corn starch, organic agave inulin, organic tara gum (fruit extract), salt, soy peptones, stearic acid, sugar.
Contains: Milk and Soy
Contains a unique novel food ingredient.
Distributed by: Quincy Bioscience Holding Company, Inc., Madison, WI 53717, USA
Suggested use: Take one tablet daily in the morning, with or without food.


This item is
64
electronically protected
Originally discovered in jellyfish, Prevagen® is now produced in a controlled scientific process. Now with Vitamin D.
*Based on a clinical study of subgroups of individuals who were cognitively normal or mildly impaired.
*THESE STATEMENTS HAVE NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE OR PREVENT ANY DISEASE.


Prevagen
CHEWABLES
Healthier Brain. Better Life.
Prevagen® Chewables is designed for great-tasting mixed berry flavor.
Safe & Clinically Tested Ingredient
Only One Tablet Per Day
Full 30 Day Supply
Prevagen Chewables is formulated with apoaequorin, which uniquely supports brain function.* In a computer-assessed, double-blinded, placebo-controlled clinical study, Prevagen improved certain aspects of cognitive function over a 90 day period.*
www.prevagen.com
Questions? Call 888.565.5385 or visit www.prevagen.com

Supplement Facts

Serving Size: 1 tablet

Amount per tablet		% Daily Value
Total Carbohydrate	1 g	<1%**
Vitamin D (as D3 cholecalciferol)	50 mcg	250%
Apoaequorin	10 mg	†

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

Other Ingredients: Sorbitol, mannitol, natural flavors, contains 2% or less of: annatto extract (for color), casein peptones, lactose, magnesium stearate (vegetable source), maltodextrin, modified corn starch, organic agave inulin, organic rebaudioside A (stevia extract), salt, soy peptones, stearic acid, sugar.

Contains: Milk and Soy

Contains a bioengineered food ingredient.

Distributed by: Quincy Bioscience Holding Company, Inc., Madison, WI 53717, USA

Suggested use: Take one tablet daily in the morning, with or without food.

55. And if one clicks on a product label on the website, one will see identical side panels with the only difference being that the extra strength doses are claimed to be "designed to have twice the apoaequorin as Prevagen regular strength" – no other statements as to how the extra dosing

might provide more or different benefits.[10]

56. One of the side panels on the Prevagen boxes states: "PREVAGEN – Healthier Brain. Better Life" which is followed underneath by "Safe and Clinically Tested Ingredient … Prevagen is formulated with apoaequorin, which uniquely supports brain function. In a computer-assessed, double-blinded, placebo-controlled clinical study, Prevagen improved certain aspects of cognitive functions over a 90 day period." And this same message is conveyed on a page that contains this link.[11]

57. These same messages are on Prevagen packaging.

58. As the above illustrates, Prevagen is available in regular strength, extra strength, and mixed berry flavor chewable forms. The regular strength and mixed berry flavor products contain 10 mg of apoaequorin per serving, while the extra strength products contain 20 mg of apoaequorin per serving. A 30-count bottle of 10mg doses of Prevagen retails for $39.95 (a 60-count bottle sells for $74.95) and extra-strength sells for $59.95 for a 30-count bottle (and $109.95 for a 60-count bottle).

59. While Defendants have routinely changed the physical makeup of the boxes and bottles over time, the same brain health messages have always been conveyed as the ones discussed above along with the separately actionable misrepresentations that Prevagen is clinically tested.[12]

60. And throughout the relevant time period (class period),

---

[10] https://prevagen.com/products/prevagen-regular-strength-brain-health-memory-supplements (last visited February 26, 2024).

[11] https://prevagen.com/products/prevagen-regular-strength-brain-health-memory-supplements (last visited February 26, 2024).

[12] Earlier versions said "clinically shown" but as part of a Florida-based claims made settlement that paid the class approximately $900,000.00 and the lawyers approximately $2,500,000.00, Defendants agreed to a meaningless change in the wording to "clinically tested." The class here does not include any of the purchases that were subject to this prior class settlement.

Defendants have consistently conveyed the same message to consumers throughout the United States, including California, that Prevagen is "clinically tested" to "improve[] memory" and "support[]: healthy brain function, sharper mind, and clearer thinking" simply by taking a recommended daily dosage.

61. Defendant's brain function and memory representations are false, misleading, and deceptive as are the clinically tested representations.

62. Yet, each and every consumer who purchases these Products at a brick-and-mortar store[13] or online, is exposed to the deceptive brain function and memory representations, which appear prominently and conspicuously on the front of each Prevagen box as discussed above as well as on Defendants' website and on TV.

63. All of the above statements are false as (1) Prevagen does not supplement additional proteins for the brain to use; (2) the apoaequorin in Prevagen is not a protein that "uniquely supports critical brain functions: and (3) more fully set forth below clinical studies do not support the wildly false claims about Prevagen and brain health/function representations made by Defendants.

64. Each Prevagen product is essentially the same, as each contains the same active ingredient, apoaequorin, and as set forth herein, whether the product contains 10mg or 20mg of apoaequorin makes no difference because the apoaequorin contained in each is worthless for the same reasons – once ingested, apoaequorin, in either capsule, chewable form or any form Defendants might choose, is completely digested into common amino acids and in this sense is no different from any other dietary protein.

[13] On its web site Quincy claims that Prevagen is sold in over 50,000 stores nationwide.

65. And if, for some reason, some completely intact molecules of apoaequorin survived the enzymatic onslaught that happens during digestion – which even Defendants admitted was not possible in a filing before the FDA in 2016 – and even if some of these molecules did not get snatched up by the over 1 trillion cells in our bodies and somehow ended up near the brain, they would not be able to gain entry into the brain because the blood brain barrier ("BBB") would block entry.

66. Thus, the most compelling reason why Prevagen cannot do what Defendants claim it does is found in well-accepted body chemistry science – apoaequorin, a dietary protein, is digested into common amino acids just like most other – non-allergenic- dietary proteins and can make no more contribution to brain health than a piece of baloney, turkey or hamburger – and very small pieces at that.

67. Once digested, apoaequorin is no longer apoaequorin, is not a calcium-binding protein (the feature that was the reason that Underwood believed apoaequorin works to provide brain health benefits), and instead becomes elementary amino acids. As a result, it is incapable of providing the purported brain health, function, and memory benefits.

In 2016, Defendants Admitted to the FDA that Prevagen is Completely Digested into Amino Acids Like Other Dietary Proteins – Or in Other Words – Prevagen Cannot Work as Represented[14]

[14] While the FDA has not taken direct action against the Defendants and closed its files in 2018, in 2017 the FTC filed an action that is set for trial in the near term pending in the Southern District of New York, seeking to enjoin Defendants from making some of the false and deceptive representations set forth herein. *FTC et al. v. Quincy Bioscience et al.*, No. 1:17-cv-00124-LLS (S.D.N.Y.). Since private plaintiffs cannot bring injunctive relief claims for consumer fraud claims (*See Conrad v. Boiron*, 869 F.3d 536, 542 (7th Cir. 2017) the claims asserted herein do not overlap those of the FTC case which, in turn, is precluded from seeking monetary

68. In another warning letter sent on November 21, 2013, the FDA noted that since the apoaequorin sold as Prevagen was synthetically made it was not a recognized food that humans had eaten on a large scale basis – precluding it from being sold as a dietary supplement.

69. The primary issue raised by the FDA in this regard was whether apoaequorin was allergenic.

70. In response to this letter, Defendants engaged experts to (1) conduct various commonly relied upon digestion studies of Prevagen and (2) interpret the results of these studies as well as other scientific evidence to determine whether apoaequorin was allergenic.

71. The results of these digestion studies were presented to the FDA by Defendants in an August 2014 letter.

72. This document – called a GRAS letter (Generally Accepted As Safe) was submitted to the FDA and was signed and approved by the President of Quincy Bioscience LLC, Defendant Mark Underwood.

73. The report from the experts contained in this GRAS letter opined that synthetic apoaequorin is "no more allergenic than other non-allergenic dietary proteins and similar to other common dietary proteins because Apoaequorin is digested or hydrolyzed to individual amino acids and then absorbed in the digestive tract."

74. Their studies also suggested that the digestion characteristics of apoaequorin were similar to those of common non-allergenic dietary proteins.

---

relief (See *AMG Capital Management, LLC v. Federal Trade Commission*, 141 S. Ct. 1341 (2017). The State of New York has a claim for damages on behalf of New York residents in the above referenced FTC action against Defendants, and would overlap the damages claims here on behalf of New York residents. If the State of New York prevails *and* recovers damages on behalf of New York residents, Plaintiffs will not seek recovery for consumers in the State of New York.

75. Simply stated, the above statements provided to the FDA by Underwood and Quincy in its effort to convince the FDA that apoaequorin is not allergenic, asserted that apoaequorin is not allergenic because it is completely digested and, in turn, this document submitted by Quincy and Defendant Underwood, constitute admissions on Defendants' part that Prevagen cannot and does not work as they represent, as if apoaequorin is completely digested into common amino acids it cannot work as represented any better than any other common dietary protein.

76. Moreover, the number of amino acids derived from one dose of 10mg or 20mg Prevagen is trivial in terms of any other nutritional benefits let alone brain health benefits.

77. Our daily protein intake is approximately 75,000mg, yet the amount of amino acids produced by the digestion of a Prevagen 10mg dose is about 1/7500 or about 0.013% (0.025% for a 20mg dose) of the average intake of dietary intake of proteins.

78. Yet, a 10mg dose of Prevagen costs over $1.00, making Prevagen a grossly overpriced dietary protein.

79. By way of comparison a hot dog wiener which costs about $.50 - $.75 contains about 5000mg of protein or 500 times the protein of a Prevagen 10mg dose – even a piece of white bread contains over 200 times the amount of protein than a 10mg dose of Prevagen.

80. At $.50 per hot dog, 10 mg of hot dog would cost approximately $0.001 per mg or $0.01 per 10mg, whereas 10mg of Prevagen costs approximately $1.33.

81. In addition, if apoaequorin supposedly has the ability to supply calcium-binding proteins to the brain, Defendant's 2016 GRAS letter to the FDA put that lie to rest as they admitted that (1) the amount of calcium bound by Prevagen at either 10mg or 20mg doses "will be very small

(negligible)" and (2) after calculating the amounts of calcium bound by Prevagen the letter states, "the daily recommended allowance of calcium is 1200mg and is over 10,000 fold higher" (*Id.*) which means that the calcium-binding potential of a dose of Prevagen does not even qualify to be designated "trivial."

82. But, if one is to believe Defendants and as Mr. Underwood as set forth in his book discussed above, the whole reason for the "invention" of Prevagen was that apoaequorin is a calcium-binding protein and that our brains could use more calcium-binding proteins as we age.

The Blood-Brain Barrier Would Block Any Intact Apoaequorin That Reaches the Brain

83. Moreover, even if somehow some intact apoaequorin molecules did survive digestion, if they did not cause anaphylactic shock like undigested peanut molecules, those molecules would more than likely be snatched up by any of the approximate 1 trillion cells in our bodies before they reached the brain.

84. And as noted above – the BBB blocks molecules like apoaequorin.

85. Plaintiff and his counsel have retained one of the world's foremost experts in brain chemistry and an expert in the field regarding whether and how substances may or may not affect brain function and memory.

86. He has evaluated the ingredients in Prevagen, along with reviewing the various iterations of the MMS study.

87. Plaintiff's expert has concluded that (1) Prevagen cannot work as represented because the apoaequorin, the only purported active ingredient in Prevagen, once ingested, is completely destroyed by the digestive system, transforming it into common amino acids (and maybe a

few small peptides – combinations of two amino acids) no different than those derived from other common food products such as chicken, cold cuts, hamburgers etc.; (2) the average diet contains 50-100 grams of protein per day, contains all the required amino acids, and provides about 50,000-100,000 times more amino acids than Prevagen and, as a result, any amino acids derived from the digestion of Prevagen would be massively diluted and could have no measurable effect on the brain; (3) ingestion of Prevagen cannot and does not have any effect on brain function or memory; (4) the Madison Memory Study is deeply flawed because, among other things, the post-hoc subgroup conclusions relied upon by Defendants violated established clinical trial principles as well as not being supported by the study and (5) if it is to be relied upon for anything it proves that Prevagen does not work as represented because the original endpoint – whether Prevagen provided any brain health benefits – was shown to be negative.

88. As a result, Defendant's citation to this subgroup analysis in its marketing as described herein, leading consumers to believe that Prevagen has been proven to work as represented, its a separate false, misleading and deceptive statement that is in addition to the false claims made by Defendants that Prevagen provides any sort of brain health benefits.

"Clinically Tested" Coveys the Message that Prevagen is Clinically Shown/Proven To Provide the Represented Brain Health Benefits

89. Throughout the Prevagen packaging and other marketing Defendants make numerous references to the MMS and the fact that Prevagen has been proven effective for slowing down mild cognitive decline or even improving cognitive performance in those with mild cognitive decline.

90. Though not disclosed to consumers, this claim, in turn, was based on an unplanned post-hoc subgroup analysis of the MMS. This, of

course, is a convenient subgroup finding for Defendants to use to promote Prevagen, as their customers are comprised mostly of people who are concerned with memory issues.

91. The Prevagen front label packaging states that the Product is "clinically tested" to provide brain function and memory benefits. By stating that the product is clinically tested, Defendants are representing to consumers that credible scientific evidence exists which supports Defendant's claim that the product provides brain function and memory benefits. Otherwise, why make a "clinically tested" claim in the first instance?

92. Reasonable consumers understand "clinically tested" to mean that there is competent and reliable scientific support for the brain function and memory benefit representations as there could be only two relevant outcomes of clinical testing – either Prevagen was shown to work as represented or not, and reasonable consumers would not conclude that Defendants intended to inform them that the clinical testing proved that Prevagen did not work.

93. Thus, reasonable consumers would conclude that the fact that Defendants represent that Prevagen was clinically tested means that the testing showed positive results and that Prevagen will provide the represented brain health benefits.

The MMS Is A Deeply Flawed Study as is the Subgroup Analysis Cited By Defendants In their Market Materials

94. The Madison Memory Study ("MMS") and the various differing written reports issued by Defendants over the years about it, are not the by-product of a legitimate clinical study or accepted scientific analysis.

95. Its results are so flawed as to be wholly unreliable to reach any conclusions about the efficacy of apoaequorin. In fact, if the study is to be relied upon at all, its results show that apoaequorin does not work as represented.

96. For at least the last 70 years, the universally accepted form of scientific evidence recognized by experts in the field for determining whether a substance provides any human health benefits is through demonstrating that it has a statistically significant value over placebo based high quality and well-conducted randomized controlled clinical trials ("RCTs").

97. The MMS is none of the above.

98. Experts in the field of brain health research would require that any brain health benefits claimed for substances like Prevagen be proven by at least one and, under the well-accepted scientific "principle of replication",[15] most often, two well-conducted randomized controlled clinical trials.

99. This well-settled science, in turn, requires that any conclusions derived from an RCT must be ones based upon the testing of pre-planned hypotheses set forth in a protocol prepared before the study.

100. For example, the protocol of the 2016 version of the MMS report appears to set forth the hypothesis it was testing whether, when the results from the whole group of 218 study subjects were analyzed as a group, there was a statistically significant difference between the Prevagen group and the placebo control group over a variety of endpoints.

[15] The scientific principal that many are taught in high school biology, that before reaching conclusions, an experiment's results should be replicated.

101. What is also clear is that the protocol did not specify – on an a priori basis – that any subgroup analyses would be performed on those with no or mild cognitive decline. Instead, as will be discussed below, the subgroup analysis cited by Defendants was an improper post-hoc analysis of the data that has the common name "data-mining" – looking for a positive result when none were found per the protocol.

102. While such post-hoc analyses are routinely performed, particularly when a study is negative, they are not to be relied upon for any conclusions to be derived from the study itself but, instead, at most provide new hypotheses to be subsequently tested in later RCTs.

103. In particular, any efficacy analyses of sub-groups must have been pre-planned in the original protocol of the study and adequately powered to avoid false positive results.

104. The sub-group analysis cited by Defendants was not pre-planned but instead was part of numerous post hoc analyses of various small subsets of study participants which Defendants performed until they found a subset they liked.

105. And finally, just as important, post-hoc analyses are deemed unreliable for reaching efficacy conclusions because of the risk of data mining – which is what happened here.

106. So, for example, if Defendants really believed that their post hoc analysis on this subgroup might have merit, it was incumbent upon them to conduct a high-quality RCT studying whether Prevagen provided brain health benefits to those with no or mild cognitive declines. That they did not do so, says much about the confidence they have in such a subgroup RCT producing any positive results.

107. But the improper citation and reliance on the subgroup analysis by Defendants should not obscure that the results for the one hypothesis the

study did test – how did Prevagen perform when the entire study group is analyzed, resulted in Defendants writing this in their 2016 published version of the MMS – "no statistically significant results were observed over the entire study population." And in the results section, they acknowledged that this was true for every endpoint that they studied – no statistical differences at all.[16]

108. In fact, it was only after the study results showed no efficacy for the original hypothesis that Defendants went on a data-mining excursion and found that there were purported statistically significant results in one subgroup when their results were combined, and which subgroup Defendant contends comprise individuals "with either minimal or no cognitive impairment."

109. And apart from being the by-product of improper data-mining there is another reason why trying to differentiate between different subgroups that are grouped by AD8 status is improper as well.

110. Because, as discussed here, the persons tasked with conducting the MMS were not qualified to conduct clinical trials, they chose a device to categorize individual study subjects' cognitive status at baseline (the beginning of the study) and at several points during the study (midpoints and the end) called the AD8.

[16] Quincy paid for the publication of this 2016 version of the MMS in Advances in Mind-Body Medicine, at best, a fringe journal that appears to make money only by authors paying them to publish. Peer-reviewed journals are ranked on their impact (measured by the times that articles published in their journals are cited). The New England Journal of Medicine has a 176.08 impact factor, the JAMA has a 157.3 impact factor, and the British Journal of Medicine is 96.2. The Advances journal has an impact rating of 0.132.

The AD8 is a Preliminary Screening Device That Is to be Used to Determine Whether Further, More Definitive Testing is Required and is Not To Be Used As it Was in the MMS

111. Defendants used the AD8 to categorize the study subject from no cognitive impairment to severe cognitive impairment.

112. But the AD8 is not to be used for the purposes it was employed by the Defendants in the MMS.

113. The AD8 is a basic screening tool that was originally designed to be administered by persons such as family members to assess whether they should seek further, more accurate, testing by medical professionals.

114. So, but for a few exceptions not applicable to the MMS, all the AD8 is to be used for is to determine whether or not more precise diagnostic testing should be conducted on an individual to evaluate their cognitive status.

115. Thus, the AD8 sets forth 8 levels of cognitive status – with 1 being the healthiest and 8 being the least healthy.

116. But it is not a diagnostic tool, as it has been found to be wrong as much as 50% of the time in terms of where a patient is situated on the cognitive status spectrum.

117. This means that, as a threshold matter, there is a chance that 50% of the MMS study subjects were placed in the wrong AD8 category, which in turn means that any analysis of the effects of Prevagen on any subgroups are automatically unreliable to arrive at any conclusions regarding Prevagen's efficacy within such subgroups.

118. Moreover, a recent meta-analysis of the AD8 found that it has "small informational value in confirming MCI (mild cognitive impairment) and dementia but moderate informational value in excluding it." *See* "The Diagnostic Accuracy of the Ascertain Dementia 8 Questionnaire for

Detecting Cognitive Impairment," attached as **Exhibit 6**. Yet, it was used in the MMS to recruit subjects with MCI and the subgroup analysis (the persons categorized by Defendants as AD02 patients) claimed to include persons with MCI.

119. This meta-analysis also found that, "The AD8 had greater sensitivity in differentiating normal cognition from MCI or dementia when used in clinics or hospitals than when used in the community." The MMS was conducted on community dwelling older adults.

The People Who Designed, Conducted and Analyzed the MMS Were Not Qualified to Conduct an RCT

120. The MMS study's problems also include the fact that it was designed, conducted, analyzed and written up by persons with no training, expertise or experience in clinical trials. This in turn likely describes why it was so unscientific and deeply flawed.

121. The person who seems to have been primarily responsible for designing and conducting the various clinical trials on Prevagen[17] including the MMS, was Taylor Gabourie – who had a bachelors degree in psychology while she was with Quincy and conducting this study.

122. According to her LinkedIn page, she is currently the AMR Communications Officer at the World Organization for Animal Health and lists her title at Quincy as "Statistical Research Coordinator" who according to her was "the *main* resource at any stage of the research process including: being knowledgeable of all protocols, regulations, ethical standards, processes/procedures and individual colleagues [sic] responsibilities." *See* **Exhibit 7**, attached hereto.

[17] There appear to have been numerous others, other than the cognitive study, including ones for the treatment of diseases such as MS.

123. And the person who purportedly supervised her on the MMS study, Kenneth Lerner, was no better. Mr. Lerner states on LinkedIn that his latest degree is an MBA in marketing and who identifies himself on LinkedIn as being the head of "Business development and Intellectual Property Manager" for Quincy Bioscience since 2006 with his prior positions being "Intellectual Property and Technology Transfer Manager" at the University of Wisconsin Milwaukee (1999-2006) and Business and Corporate Development Manager at Ophidian (a pharmaceutical company) (1993-1999). He lists no experience with clinical trials and, in fact, lists his responsibilities at Quincy as "Diplomacy – drug development[18] budget preparation, legal protection, patent applications, trademark law, trademark infringement, international intellectual property, intellectual property law, patent portfolio management and trademarks.' *See* **Exhibit 8**, attached hereto.

124. In short, neither of the two persons listed as the chief "investigators" for the MMS had any experience designing, conducting or evaluating the results of a clinical trial. Two other authors of the 2016 report of MMS are a person who was in charge of the manufacturing of Prevagen and Defendant Mark Underwood who has a B.A. and whose prior work experience before Quincy was working as a "Director of Business Development" at a packaging company.

125. As a result, the MMS is riddled with critical and fatal flaws as described herein, and should not and cannot have been relied upon by the Defendants for the marketing purposes for which it was used by the Defendants.

[18] Drug development being an interesting term as Quincy sells only one thing – a dietary supplement – Prevagen.

Per Its Protocol, the MMS was a Negative Study

126. What should not be missed is that the MMS study was a negative study as far as Prevagen working as Defendants represent.

127. The clinical trial has a pre-stated protocol that sets forth what hypothesis is being studied and then governs how that it is to be studied and what conclusions can be drawn from the results. MMS stated that its purpose was to test the effect of Prevagen on the entire 218-person study group, without regard for their purported cognitive status based on the AD8.

128. And, when looking at the results of the entire study group as was originally planned in the protocol, Quincy admitted in a published 2016 version of the study that "no statistically significant results were observed over the entire study populations." In short, no statistically significant results were observed in the treatment group over the entire study population on any of nine cognitive tasks.

129. That should have been the end of the inquiry and the analysis of the data from the MMS – Prevagen did not work for the study group as set forth in the protocol.

130. Or to put it simply – the MMS study was a negative study that showed that Prevagen does not work as represented.

Defendants Engaged In and Then Relied On Improper Post-hoc Data Mining to Arrive At Their AD8 01-02 Subgroup Analyses As Well as Using An Improper Statistical Significance Standard

131. But more important, this sort of data mining and post-hoc analyses are considered by experts in the field to be wholly improper for purposes of reaching any efficacy conclusions.

132. Some of the reasons for this are that only at the planning state can it be determined – using well-accepted biostatical analyses – whether a

study group is large enough or a subgroup is adequately "powered" such that conclusions about efficacy can be made. As without adequate pre-planned powering, a post-hoc analysis of a subgroup risks false positives.

133. If subgroups are also to be studied, different biostatistical analyses must be pre-planned and employed for each subgroup.

134. The same is true when a study attempts to analyze multiple endpoints. Thus, if a study investigates multiple endpoints – say two – to reach statistical significance the results must be 0.025 – twice as stringent than the usual 0.05. Or in other words, the analysis must find that its conclusions are correct 97.75 of the time as opposed to being correct 95%. The above corrections are called "Bonferroni corrections" and are employed when more than one endpoint is being studied in a single RCT.[19]

135. There were so many endpoints studied in the MMS – over 30 in some versions and at least 4 in the 2016 study published in Advances – that the statistical significance that would be required to be met to make any conclusions about the efficacy of Prevagen for any subgroups would have to be close to 0.00 or to put it in lay persons' terms – it would have to be correct 100% of the time. Just four endpoints would require a statistical significance level of 0.0125 – a statistical level that was not used in the

[19] The Bonferroni test, also known as "Bonferroni correction" or "Bonferroni adjustment" "suggests that the p- value for each test must be equal to its alpha divided by the number of tests performed. The Bonferroni test is a multiple-comparison correction used when several dependent or independent statistical tests are being performed simultaneously. The reason is that while a given alpha value may be appropriate for each individual comparison, it is not appropriate for the set of all comparisons. In order to eliminate multiple spurious positives, the alpha value needs to be lowered to account for the number of comparisons being performed." https://www.investopedia.com/terms/b/bonferroni-test.asp.

subgroup analysis.

136. As an article in the Food and Drug Law Institute – "After Quincy failed to find a treatment effect for the study population as a whole, its researchers conducted more than 30 unplanned *post hoc* subgroupanalyses of the results,[21] looking at data broken down by several variations of small subgroups for each of the nine cognitive tasks. This is a classic example of data dredging or "p-hacking," where researchers perform unplanned analysis following the rejection of an overall null hypothesis with the goal of finding significant effects wherever and however they can be found. [22] If one conservatively assumes 31 subgroups from the "more than 30" subgroup range, the probability of finding at lease one false positive at the 0.05 level of statistical significance ("alfa") is the family-wise error rate (FWER) = p =1–(1-0.05) =).796 = 80%. An 80% probability of finding at lease one false positive in an unlaced post hoc subgroup analysis provides compelling evidence of a deficiency in the study's methodology. As such, *post hoc* subgroup analysis is suitable only for generating new hypotheses for future studies; thus, it is inappropriate for generating definitive results and establishing Prevagen's efficacy in the Madison Memory Study.[23]" Degnan *et al.*, "Strengthening the Regulations of Dietary Supplements – Lessons from Prevagen," Food and Drug Law Institute, Winter 2021, attached hereto as **Exhibit 9**.

137. And as for the subgroup analysis cited by Defendants in their marketing of Prevagen, the authors of this article note that, "Given the 80% minimum Type 1 error rate previously calculated for 30-plus comparisons, these statistically significant findings are very likely false positive and not reliable evidence of a treatment effect. (¶) The final and decisive shortcoming of Quincy's subgroup analysis was its failure to use multiple testing procedures to control for family-wise error rate (FWER). [fn] These

procedures include the Bonferroni correction and the Benjamin-Hochberg (B-H) methods and are well-known in statistical practice…Compared to the Bonferroni and B-H criteria, the results for subgroups AD8 0-1 and 0-2 are in fact not statistically significant; therefore, Prevagen's efficacy cannot be proved both in the study subgroups and in the entire study population." *See* **Exhibit 9**, Degnan *et al.*, at p. 4 of the exhibit, (emphasis in original).

138. And while clinical trials are routinely conducted – testing multiple endpoints – when they get to be as large as the number tested in the MMS, such a study can only be used for exploratory purposes to find a hypothesis that might later be tested in an RCT – like that Prevagen is effective for those with MCI. But for any number of reasons, the subgroup analysis relied upon by Defendants to make the representations they do about Prevagen are wholly improper.

139. Moreover, although any properly conducted clinical trial uses biostatistics and persons with expertise in biostatistics to determine whether there are sufficient numbers of study subjects such that the study is sufficiently powered to be relied upon, there is no discussion of any such powering calculations for the MMS as a whole and by definition, given that the subgroup analyses were not pre-planned and were post-hoc, they could not and did not have any of the required per protocol pre-planned powering calculations.

140. Powering calculations are routinely discussed in reliable RCTs, so that other scientists and biostatisticians who might read the study report can determine whether the statistical analyses employed were proper. In fact, this is the process of science – articles are published so that the world of scientists can review or even replicate the experiments reported in a study report.

141. Thus, it must also be assumed that in the absence of any

powering discussions in the published version of the MMS that no powering was performed at all – yet another fatal flaw in the MMS as a whole and the subgroup analysis cited by Defendants in their marketing of Prevagen.

142. As a result, the subgroup analyses relied upon by Defendants to claim efficacy for those with mild cognitive problems cannot and should not be relied upon for such conclusions.

143. Thus, Defendants' claims about Prevagen being clinically tested, which in turn means to the reasonable consumer that Prevagen is clinically shown to provide the represented brain health claims are themselves false, misleading, and deceptive statements independent of the brain health falsehoods/representations.

Summary of Key Points

144. The only reason a consumer would purchase Prevagen is to obtain the advertised brain health benefits, which it does not provide.

145. Defendants advertise and promote Prevagen with the brain health claims – "improves memory" and "supports healthy brain function, sharper mind and clearer think" – prominently displayed on the front of the package.[20]

146. The fact that Defendants prominently advertises Prevagen's purported brain health benefits on the front label (as opposed to only on the back label), in bold text, demonstrates that Defendants are aware that its consumers specifically seek out supplements to improve their brain health, cognitive functions, and memory and they are actively promoting their brain health claims to consumers.

[20] https://prevagen.com/collections/brain-health-memory-improvement-supplements (last visited February 26, 2024).

147. Otherwise, Defendants would not devote limited and valuable labeling real estate to such claims. Indeed, the brain health claims are the only marketing claims made on the products' front labels.

148. Defendants intended for Plaintiff and the Class members to be deceived or misled by the brain health, brain function, and memory representations. Defendants' deceptive and misleading practices proximately caused harm to the Plaintiff and the Class.

149. As a result of Defendants' false, misleading, and deceptive brain health, brain function, and memory representations, consumers – including Plaintiff and members of the proposed Class – have purchased Products that do not perform as advertised and are worthless for purposes of brain health, brain function, or improving/maintaining memory.

150. Whether a product is clinically tested or not is also important information to a reasonable consumer and they would not have purchased Prevagen if they were aware of the false, misleading, and deceptive representations and labeling of the products by Defendants.

151. Plaintiff bring this action on behalf of himself and other similarly situated consumers who purchased Prevagen, to obtain redress for those who have purchased Prevagen from July 22, 2020 forward.[21] Plaintiff and members of the Proposed Class were injured by Defendants' false, fraudulent, unfair, deceptive, and misleading practices and conduct. Accordingly, Plaintiff seeks compensatory damages and equitable remedies

[21] July 22, 2020 is the end date of a claims made class action settlement that could not have achieved approval in any circuit but for the Eleventh Circuit which at the time permitted a settlement that paid the class under $1 million but the attorneys close to $2.6 million. While the Prevagen settlement was not objected to, since then the Eleventh Circuit rejected a similar settlement entered into by the same plaintiffs' attorneys for another brain health supplement with similar dismal results for the class. *See Williams et al. v. Reckitt Benskiser LLC et al.*, No. 22-11232 (11th Cir. Apr. 12, 2023).

for themselves(s) and members of the Proposed Class.

JURISDICTION AND VENUE

152. 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 some members of the Class are citizens of a state different from Defendants.

153. This Court has personal jurisdiction over Defendants because the corporate Defendants are authorized to conduct and do business in California, including this District. And it was the individual Defendants who caused Prevagen to be marketed, promoted, distributed, and sold in California. As a result, Defendants have sufficient minimum contacts with this State and/or sufficiently availed themselves of the markets in this State through their promotion, sales, distribution and marketing within this State, including this District, to render the exercise of jurisdiction by this Court permissible.

154. 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 Defendants transacts substantial business in this District.

PARTIES

155. During the relevant time period, Plaintiff Richard Poole was exposed to and saw Defendant's brain function and memory representations by first hearing about them on television advertisements which led him to believe that the Prevagen products would provide him the represented brain health benefits. These brain health representations were reconfirmed when he went to a CVS store near his home, saw the front of the package labeling

which contained the same brain health representations and made his purchases of Prevagen. Within the last 3 years, Plaintiff Poole has made multiple purchases of Prevagen; Plaintiff Poole first purchased regular-strength Prevagen but then switched to extra strength after a few purchases. In all, Plaintiff purchased approximately 8 bottles of Prevagen products in the hopes that, over an extended period of time, they would provide the represented brain health benefits. After his last purchase he determined that, in fact, the Prevagen products had not and did not provide him with any brain health benefits. Plaintiff paid approximately $35 for regular strength and $45 for extra strength Prevagen. The Prevagen products Plaintiff Poole purchased did not and could not improve memory or support healthy brain function as represented. As a result, Plaintiff Poole suffered injury in fact and lost money. Had Plaintiff known the truth about Defendants' misrepresentations, he would not have purchased Prevagen.

156. Defendant Quincy Bioscience Holding Company, Inc. is a Wisconsin corporation with its principal place of business at 726 Heartland Trail, Suite 300, Madison, Wisconsin. Quincy Bioscience Holding Company, Inc. transacts or has transacted business in this district and throughout the United States. At all times material to this Complaint, acting alone or in concert with others, Quincy Bioscience Holding Company, Inc., through its wholly-owned subsidiaries, has advertised, marketed, promoted, distributed, or sold Prevagen to consumers throughout the United States, including California.

157. Defendant Quincy Bioscience, LLC is a wholly-owned subsidiary of Quincy Bioscience Holding Company, Inc. It is a Wisconsin limited liability company with its principal place of business at 726 Heartland Trail, Suite 300, Madison, Wisconsin. Quincy Bioscience, LLC transacts or has transacted business in this district and throughout the

United States. At all times material to this Complaint, acting alone or in concert with others, Quincy Bioscience, LLC has advertised, marketed, promoted, distributed, or sold Prevagen to consumers throughout the United States, including California.

158. Defendant Prevagen, Inc., also doing business as Sugar River Supplements, is a wholly-owned subsidiary of Quincy Bioscience Holding Company, Inc. It is a Wisconsin corporation with its principal place of business at 726 Heartland Trail, Suite 300, Madison, Wisconsin. Prevagen, Inc. transacts or has transacted business in this district and throughout the United States. At all times material to this Complaint, acting alone or in concert with others, Prevagen, Inc. has advertised, marketed, promoted, distributed, or sold Prevagen to consumers throughout the United States, including California.

159. Defendant Quincy Bioscience Manufacturing, LLC is a wholly-owned subsidiary of Quincy Bioscience Holding Company, Inc. It is a Wisconsin corporation with its principal place of business at 726 Heartland Trail, Suite 300, Madison, Wisconsin. Quincy Bioscience Manufacturing, LLC transacts or has transacted business in this district and throughout the United States. At all times material to this Complaint, acting alone or in concert with others, Quincy Bioscience Manufacturing, LLC has advertised, marketed, promoted, distributed, or sold Prevagen to consumers throughout the United States, including California.

160. Defendant Mark Underwood ("Underwood") is the co-founder and President of Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, and Prevagen, Inc. Underwood is a member of the Board of Directors of Quincy Bioscience, LLC, Prevagen, Inc., and Quincy Bioscience Manufacturing, LLC and a shareholder of Quincy Bioscience Holding Company, Inc., owning 33 percent of shares, the largest individual

ownership interest. Underwood, in connection with the matters alleged herein, transacts or has transacted business in this district and throughout the United States, including California.

161. At all times material to this Complaint, acting alone or in concert with others, Underwood has formulated, directed, controlled, had the authority to control, or participated in the acts and practices of Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, and Prevagen, Inc., including the acts and practices set forth in this Complaint. Underwood is a member of the marketing creative team, serving as the final decision maker on advertising claims across all channels of distribution and media platforms.

162. Defendant Michael Beaman ("Beaman") is the co-founder, former President, and current Chief Executive Officer of Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, and Prevagen, Inc. Beaman is the Chair of the Board of Directors for Quincy Bioscience, LLC, Prevagen, Inc., and Quincy Bioscience Manufacturing, LLC and a shareholder of Quincy Bioscience Holding Company, Inc., owning 22 percent of shares, the second largest individual ownership interest. Beaman, in connection with the matters alleged herein, transacts or has transacted business in this district and throughout the United States, including California.

163. Defendants Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, Prevagen, Inc., and Quincy Bioscience Manufacturing, LLC (collectively, "Corporate Defendants") have operated as a common enterprise while engaging in the deceptive acts described herein.

164. Because these Corporate Defendants have operated as a common enterprise, each of them is jointly and severally liable for the acts

and practices alleged below. Defendants Beaman and Underwood have formulated, directed, controlled, had the authority to control, or participated in the acts and practices of the Corporate Defendants that constitute the common enterprise.

CLASS DEFINITIONS AND ALLEGATIONS

165. Plaintiff brings this action on behalf of himself 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 law and/or similar laws in other states:

Nationwide Class Action

All consumers in the United States of America who since July 22, 2020 and until the date notice is disseminated, purchased Prevagen.

Excluded from this Class are Defendants and the officers, directors and employees of any Quincy related entity and those who purchased Prevagen for the purpose of resale.

Multi-State Class Action

All consumers who since July 22, 2020 and until the date notice is disseminated, purchased Prevagen in California and states with similar laws.[22]

[22] While discovery may alter the following, Plaintiff preliminarily alleges that Defendant 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.*; Fla. Stat. §501.201 *et seq.*; 815 Ill. Comp. Stat. 502/1, *et seq.*; Mass. Gen. Laws ch. 93A; Mich. Stat. §445.901 *et seq.*; Minn. Stat. §8.31 *et seq.*; Missouri Stat. §407.010 *et seq.*; N.J. Stat. §56:8-1 *et seq.*; N.Y. Gen. Bus. Law § 349; and Wash. Rev. Code. §19.86.010 *et seq.*

> Excluded from this Class are Defendants and the officers, directors and employees of any Quincy related entity and those who purchased Prevagen for the purpose of resale.

166. Alternatively, Plaintiff brings this action on behalf of himself 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 consumers in California who since July 22, 2020 and until the date notice is disseminated, purchased Prevagen.
>
> Excluded from this Class are Defendants and the officers, directors and employees of any Quincy related entity and those who purchased Prevagen for the purpose of resale.

167. ***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 Prevagen who have been damaged by Defendant's conduct as alleged herein. The precise number of Class members is unknown to Plaintiff.

168. ***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 Defendants' representations discussed above are misleading, or objectively reasonably likely to deceive;

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

(c) whether Defendants engaged in false or misleading advertising;

(d) whether Plaintiff and Class members have sustained monetary loss and the proper measure of that loss; and

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

169. ***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 Defendants' deceptive brain function and memory representations that accompanied each and every bottle of Prevagen as well as Defendants' other marketing efforts such as TV commercials. Plaintiff is also advancing the same claims and legal theories on behalf of himself and all members of the Class.

170. ***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.

171. ***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 Defendant. It would thus be virtually impossible for members of the Class, 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.

172. Unless a Class is certified, Defendants will retain monies received as a result of their conduct that was taken from Plaintiff and Class members.

FIRST CAUSE OF ACTION

Violation of Business & Professions Code §17200, *et seq.*

(By Plaintiff Against Defendants)

173. Plaintiff and Class members reallege and incorporate by reference each allegation set forth above and further allege as follows.

174. Plaintiff brings this claim individually and on behalf of the Class.

175. As alleged herein, Plaintiff has suffered injury in fact and lost money or property as a result of Defendants' conduct because he purchased Prevagen in reliance on Defendants' claim that Prevagen is "clinically tested" to "improve[] memory" and "support[]: healthy brain function, shaper mind, and clearer thinking" but did not receive a product that improved memory and supported brain function, sharper mind and clearer thinking.

176. The Unfair Competition Law, Business & Professions Code §17200, *et seq*. ("UCL"), and similar laws in other states, prohibits any "unlawful," "fraudulent" or "unfair" business act or practice and any false or misleading

advertising.

177. In the course of conducting business, Defendants committed unlawful business practices by, *inter alia*, making the brain function and memory representations (which also constitutes advertising within the meaning of §17200), as set forth more fully herein, and violating Civil Code §§1572, 1573, 1709, 1711, 1770(a)(5), (7), (9) and (16) and Business & Professions Code §§17200, et seq., 17500, et seq., and the common law. Plaintiff and the 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.

178. In the course of conducting business, Defendants committed "unfair" business practices by, *inter alia*, making the brain function and memory representations (which also constitutes advertising within the meaning of §17200) regarding Prevagen in its advertising campaign, including the Products' packaging, as set forth more fully herein. There is no societal benefit from false advertising, only harm. Plaintiff and other Class members paid for brain function and memory benefits supported by clinical testing, which they did not receive. While Plaintiff and Class members were harmed, Defendants was unjustly enriched by its false representations. Because the utility of Defendant's conduct (zero) is outweighed by the gravity of the harm Plaintiff and Class members suffered, Defendant's conduct is "unfair" having offended an established public policy. Further, Defendants engaged in immoral, unethical, oppressive, and unscrupulous activities that are substantially injurious to consumers.

179. Further, as stated in this Complaint, Plaintiff alleges violations of consumer protection, unfair competition and truth–in–advertising laws resulting in harm to consumers. Defendants' acts also violate and offend the public policy against engaging in false and misleading advertising, unfair competition and deceptive conduct towards consumers. This conduct constitutes violations of the unfair prong of Business & Professions Code §17200, et seq.

180. There were reasonably available alternatives to further Defendant's' legitimate business interests, other than the conduct described herein.

181. Business & Professions Code §17200, et seq., also prohibits any "fraudulent business act or practice."

182. In the course of conducting business, Defendants committed "fraudulent business acts or practices" by, *inter alia*, making the brain function and memory representations (which also constitutes advertising within the meaning of §17200) regarding Prevagen in its advertising campaign, including the Products' packaging, as set forth more fully herein.

183. Defendants misrepresented on each and every Product package that the Prevagen is "clinically tested" to "improve[] memory" and "support[]: healthy brain function, shaper mind, and clearer thinking" when, in fact, oral supplementation with apoaequorin never gets past the stomach, never gets to the brain and cannot provide the brain function and memory benefits represented by Defendants.

184. Defendants' actions, claims and misleading statements, as more fully set forth above, were also false, misleading and/or likely to deceive the consuming public within the meaning of Business & Professions Code §17200, et seq.

185. Plaintiff and other members of the Class have in fact been deceived as a result of their reliance on Defendant's material representations, which are described above. This reliance has caused harm to Plaintiff and other members of the Class who each purchased Prevagen. Plaintiff and the other Class members have suffered injury in fact and lost money as a result of these unlawful, unfair, and fraudulent practices.

186. As a result of its deception, Defendants have been able to reap unjust revenue and profit.

187. Unless restrained and enjoined, Defendants will continue to engage in the above-described conduct. Accordingly, injunctive relief is appropriate.

188. Plaintiff, on behalf of himself, all others similarly situated, and the general public, seeks restitution of all money obtained from Plaintiff and the members of the Class collected as a result of unfair competition, an injunction prohibiting Defendants from continuing such practices, corrective advertising and all other relief this Court deems appropriate, consistent with Business & Professions Code §17203.

PRAYER FOR RELIEF

Wherefore, Plaintiff prays for a judgment:

1. Certifying the Class as requested herein;
2. Awarding attorneys' fees and costs;
3. An award of Plaintiff's and the class's damages; or
4. Awarding restitution and disgorgement of Defendant's revenues to Plaintiff and the proposed Class members as unjust enrichment; and
5. Providing such further relief as may be just and proper.

Dated: February 26, 2024

THIGPEN LEGAL, P.C.

By: */s/ Jordanna G. Thigpen*
Jordanna G. Thigpen
9595 Wilshire Blvd. Suite 961
Beverly Hills, CA 90212
T: (310) 210-7491
Email: jt@thigpenlegal.com

HART MCLAUGHLIN & ELDRIDGE

By: */s/ Stewart M. Weltman*
Steven A. Hart, Partner
To be admitted pro hac vice
Stewart M. Weltman, Of Counsel
To be admitted pro hac vice

One South Dearborn, Suite 1400
Chicago, Illinois 60603
T: (312) 955-0545
Email: sweltman@hmelegal.com
Email: shart@hmelegal.com

LEVIN SEDRAN & BERMAN LLP

By: */s/ Charles E. Schaffer*
Charles E. Schaffer, Esq.
To be admitted pro hac vice

510 Walnut St., Ste. 500
Philadelphia, PA 19106
T: (215) 592-1500
Email: cschaffer@lfsblaw.com

CUNEO GILBERT & ADUCA, LLP

By: */s/ Charles LaDuca*
Charles LaDuca, Esq.
To be admitted pro hac vice
Brendan Thompson, Esq.
To be admitted pro hac vice
4725 Wisconsin Ave., NW, Ste. 200
Washington, D.C. 20016
T: (202) 789-3960
Email: charles@cuneolaw.com
Email: brendant@cuneolaw.com

AUDET & PARTNERS LLP

By: */s/ Michael McShane*
Michael McShane, Esq.
711 Van Ness Ave., Ste. 500
San Francisco, CA 94102
T: (415) 568-2555
Email: mmcshane@audetlaw.com

Attorneys for Plaintiff

JURY DEMAND

Plaintiff demands a trial by jury on all claims and issues for which a jury trial is available.

Dated: February 26, 2024

THIGPEN LEGAL, P.C.

By: */s/ Jordanna G. Thigpen*
Jordanna G. Thigpen
9595 Wilshire Blvd. Suite 961
Beverly Hiulls, CA 90212
T: (310) 210-7491
Email: jt@thigpenlegal.com

HART MCLAUGHLIN & ELDRIDGE

By: */s/ Stewart M. Weltman*
Steven A. Hart, Partner
To be admitted pro hac vice
Stewart M. Weltman, Of Counsel
To be admitted pro hac vice
One South Dearborn, Suite 1400
Chicago, Illinois 60603
T: (312) 955-0545
Email: sweltman@hmelegal.com
Email: shart@hmelegal.com

LEVIN SEDRAN & BERMAN LLP

By: */s/ Charles E. Schaffer*
Charles E. Schaffer, Esq.
To be admitted pro hac vice

510 Walnut St., Ste. 500
Philadelphia, PA 19106
T: (215) 592-1500
Email: cschaffer@lfsblaw.com

CUNEO GILBERT & ADUCA, LLP

By: */s/ Charles LaDuca*
Charles LaDuca, Esq.
To be admitted pro hac vice
Brendan Thompson, Esq.
To be admitted pro hac vice
4725 Wisconsin Ave., NW, Ste. 200
Washington, D.C. 20016
T: (202) 789-3960
Email: charles@cuneolaw.com
Email: brendant@cuneolaw.com

AUDET & PARTNERS LLP

By: */s/ Michael McShane*
Michael McShane, Esq.
711 Van Ness Ave., Ste. 500
San Francisco, CA 94102
T: (415) 568-2555
Email: mmcshane@audetlaw.com

Attorneys for Plaintiff