## UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

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FEDERAL TRADE COMMISSION and	Case No.
THE PEOPLE OF THE STATE OF NEW YORK, by ERIC T. SCHNEIDERMAN, Attorney General of the State of New York,	COMPLAINT INJUNCTION
Plaintiffs,	EQUITABLE
v.	
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.; and	
MICHAEL BEAMAN, individually and as an officer of QUINCY BIOSCIENCE HOLDING COMPANY, INC., QUINCY BIOSCIENCE, LLC, and PREVAGEN, INC.	
Defendants.	

### COMPLAINT FOR PERMANENT INJUNCTION AND OTHER EQUITABLE RELIEF

Plaintiffs, the Federal Trade Commission ("FTC") and the People of the State of New

York, by their attorney Eric T. Schneiderman, Attorney General of the State of New York

("NYAG"), for their Complaint allege:

1. The FTC brings this action under Section 13(b) of the Federal Trade Commission

Act ("FTC Act"), 15 U.S.C. § 53(b), to obtain permanent injunctive relief, rescission or

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reformation of contracts, restitution, the refund of monies paid, disgorgement of ill-gotten monies, and other equitable relief for the acts or practices of Defendants' Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, Prevagen, Inc., Quincy Bioscience Manufacturing, LLC, Mark Underwood, and Michael Beaman (collectively, "Defendants") in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52, in connection with the labeling, advertising, marketing, promotion, distribution, and sale of Prevagen, a dietary supplement that purportedly improves memory. Prevagen contains one active ingredient, the dietary protein apoaequorin, and it is sold in a variety of strengths and forms.

2. The People of the State of New York bring this action under New York Executive Law ("NY Exec. Law") § 63(12), which authorizes their attorney, the NYAG, to bring an action for injunctive relief, restitution, damages and costs against any person or business that has engaged in repeated or persistent fraud or illegality in the conduct of his or its business, and New York General Business Law ("NY GBL") §§ 349 and 350, which authorize the NYAG to bring an action for injunctive relief, restitution and penalties whenever any person, firm, corporation or association or agent or employee thereof has engaged in deceptive business practices and false advertising. This action is brought against Defendants in connection with the labeling, advertising, marketing, promotion, distribution, and sale of Prevagen.

### JURISDICTION AND VENUE

3. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1337(a), and 1345, and 15 U.S.C. §§ 45(a) and 53(b).

This Court has supplemental jurisdiction over the NYAG's claims under 28
 U.S.C. § 1367.

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5. Venue is proper in this district under 28 U.S.C. §§ 1391(b)(2), (b)(3), (c)(2), and
(d), and 15 U.S.C. § 53(b).

### **PLAINTIFFS**

6. Plaintiff FTC is an independent agency of the United States Government created by statute. 15 U.S.C. §§ 41-58. The FTC enforces Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), which prohibits unfair or deceptive acts or practices in or affecting commerce. The FTC also enforces Section 12 of the FTC Act, 15 U.S.C. § 52, which prohibits false advertisements for food, drugs, devices, services, or cosmetics in or affecting commerce.

7. The FTC is authorized to initiate federal district court proceedings, by its own attorneys, to enjoin violations of the FTC Act and to secure such equitable relief as may be appropriate in each case, including rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten monies. 15 U.S.C. § 53(b).

8. The NYAG is authorized to take action to enjoin repeated and persistent fraudulent and illegal business conduct under NY Exec. Law § 63(12) and deceptive business practices and false advertising under NY GBL §§ 349 and 350 and to obtain equitable or other appropriate relief, including restitution, damages, disgorgement of ill-gotten monies and penalties as may be appropriate.

#### **DEFENDANTS**

9. 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

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subsidiaries, has advertised, marketed, promoted, distributed, or sold Prevagen to consumers throughout the United States, including New York.

10. 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 New York.

11. 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 New York.

12. 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 New York.

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13. 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 New York.

14. 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. Underwood coordinates advertising claim language review with counsel, translates scientific data into marketing language, and directs research programs and activities. Underwood has appeared in infomercials aired nationwide, including in New York, touting Prevagen's memory improvement benefits and has co-authored studies on Prevagen. Underwood also authored the "Brain Health Guide," a user guide disseminated nationwide, including in New York, that describes how Prevagen works and the purported science behind this dietary supplement.

15. 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

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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 New York.

16. At all times material to this Complaint, acting alone or in concert with others, Beaman 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. Beaman has given media interviews, signed research agreements, pre-approved research proposals, and reviewed Defendants' advertising, including advertising that has been disseminated nationwide, including in New York.

17. 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 and practices alleged below. These Corporate Defendants have conducted the business practices described below through an interrelated network of companies that have common ownership, officers, managers, business functions, employees, and office locations. 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.

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#### **COMMERCE**

At all times material to this Complaint, Defendants have maintained a substantial course of trade in or affecting commerce, as "commerce" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

### **DEFENDANTS' BUSINESS ACTIVITIES**

19. Prevagen is a dietary supplement containing the active ingredient apoaequorin, a dietary protein, which according to Defendants was originally obtained from a species of jellyfish called *Aequorea victoria*. Prevagen is available in Regular Strength (10 milligrams) and Extra Strength (20 milligrams) capsules and chewable versions, and Prevagen Professional (40 milligrams) capsules (collectively, "Prevagen Products").

20. A bottle of each Prevagen Product contains 30 tablets and provides a 30-day supply if taken once daily according to the product label's suggested use. The price per bottle varies depending on the seller, with prices ranging from \$24.29 to \$58.53 for Prevagen Regular Strength, \$32.17 to \$69.95 for Prevagen Extra Strength, \$16.49 to \$51.29 for Prevagen Chewable, and \$39.33 to \$68.40 for Prevagen Professional.

21. Since at least 2007, Defendants have labeled, advertised, marketed, promoted, distributed, and sold the Prevagen Products to the public and healthcare practitioners through their own websites, Prevagen.com, QuincyBioscience.com, PrevagenPro.com, PrevagenES.com, SugarRiverSupplements.com, and through health stores, pharmacies, retail stores, and retail websites, including Amazon, CVS, Duane Reade, Rite-Aid, Meijer, the Vitamin Shoppe, and Walgreens. Sales of Prevagen in the United States from 2007 through mid-2015, minus refunds, totaled \$165 million.

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22. Defendants have widely advertised the Prevagen Products through their own websites, Prevagen.com, QuincyBioscience.com, PrevagenPro.com, PrevagenES.com, PrevagenReviews.com, SugarRiverSupplements.com, and HopeTrials.com, as well as through infomercials, short form television commercials, radio, social media, newspapers, and magazines.

23. Defendants' infomercials aired frequently as the "Better Memory Show" from July 2013 to April 2015. They employed an interview format and featured Defendant Mark Underwood, explaining the problems associated with memory loss, the purported benefits of the Prevagen Products, and research purportedly supporting Defendants' memory-improvement claims.

24. Defendants' short-form television advertisements have aired nationally on broadcast and cable networks, including CNN, Fox News, and NBC, and their radio campaign includes spots on internet and satellite radio services such as Sirius and iHeartRadio.

25. Defendants have an active social media presence with accounts on Facebook, Instagram, Twitter, Pinterest, and YouTube.

26. Defendants' advertising campaign also included a 2015 "Better Memory Tour." Company representatives traveled aboard the "Prevagen Express" bus to various health food centers and health expos across the country, showcasing the Prevagen Products and Defendant Mark Underwood's Brain Health Guide, which accompanies product orders and can be downloaded from Defendants' websites.

27. Defendants have represented, among other things, through express and implied claims and consumer and expert endorsements, that the Prevagen Products improve memory and provide other cognitive benefits, and that the Prevagen Products' effects on memory and

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cognition are clinically proven. To induce consumers to purchase the Prevagen Products,

Defendants have disseminated, or caused to be disseminated, advertisements, labeling, and other marketing materials, including, but not limited to, the attached Exhibits A through F. These advertisements contain the following statements and depictions, among others:

## A. Prevagen Regular Strength Label (Exhibit A)



Supple Serving Size: 1 Servings per co	capsule	
Amount per capsul	e	% Daily Value
Apoaequorin	10 mg	†
† Daily Value not estat		

Other ingredients: white rice flour, cellulose, salt, magnesium stearate, acetic acid. Manufactured & Distributed by Quincy Bioscience 301 S Westfield Road • Madison, WI 53717 Made without COMMON ALLERGENS Suggested use: Take 1 vegetarian capsule daily in the morning, with or without food.

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### SIDE LABEL:



**BACK LABEL**:

# B. Prevagen TV Ad – "Jellyfish Protein" (Exhibits B-1 (transcript) and B-2 (video))

ON SCREEN: Memory Improvement?

ANNOUNCER: Can a protein originally found in the jellyfish improve your memory?

ON SCREEN: QUINCY BIOSCIENCE

Our Scientists Say "Yes!"

ANNOUNCER: Our scientists say yes.

ON SCREEN: Actor portrayal [Screen depicts a smiling doctor wearing a white coat, with the words "Quincy Bioscience" and "Our Scientists Say "Yes!" appearing next to the doctor. In the next scene, another doctor in a white coat is looking into a microscope. The "Actor Portrayal" disclosure appears in both scenes in small print at the bottom of the screen.]

Supports Healthy Brain Function\* [Appears in large font in the center of the screen]

\*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. [This disclosure appears briefly in a box in much smaller font at the bottom of the screen.]

ANNOUNCER: Researchers have discovered a protein that actually supports healthier brain function. It's the breakthrough in a supplement called Prevagen.

ON SCREEN: Prevagen

Supplements Brain Proteins

ANNOUNCER: As we age, we lose proteins that support our brain.

ON SCREEN: Prevagen Improves Memory

Chart [A full-screen bar chart depicts memory improving significantly over 90 days]

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ANNOUNCER: Prevagen supplements these proteins and has been clinically shown to improve memory.

ON SCREEN: Safe Effective

ANNOUNCER: It's safe and effective.

ON SCREEN: Available at Walgreens

CVS/pharmacy RITE AID

ANNOUNCER: For support of healthier brain function, a sharper mind and clearer thinking, try Prevagen for yourself today.

## C. Website Capture, Prevagen.com, December 10, 2015 (Exhibit C)

## Improve your memory with Prevagen ®\*

Prevagen can improve memory\*

Prevagen was tested in a large double-blind, placebo-controlled study using computers to assess brain performance. 218 adults over 40 years old participated in the three month study. Prevagen significantly improved learning and word recall.\*

Around the age of 40, our brain begins to need more cognitive support.\* Prevagen can improve memory within 90 days.\*

Common examples where Prevagen may help

- Walk into a room and forget why.
- Spend extra time looking for car keys or purse.
- Trouble remembering names or faces.

These are everyday examples of normal memory challenges that can come with aging. Prevagen has been tested and shown to improve memory.\*

Prevagen is a safe and effective supplement

Only Prevagen contains the patented ingredient apoaequorin, a unique protein originally obtained from a specific species of jellyfish called Aequorea Victoria found in the Puget Sound. Apoaequorin is a protein our brains need for healthy function but is diminished in the aging process.

Prevagen is very safe and extremely well-tolerated. There are no known contraindications with any supplements or medications

## Make Memories Last a Lifetime

There's nothing more fulfilling than being at your mental best in order to enjoy every moment with friends and family. But that can be difficult for some of us due to normal, age-related memory loss.

## **Order** Now

# How does Prevagen ® work?

Laboratory research has demonstrated that Prevagen has powerful cell supporting activity by providing a protein originally found in jellyfish.

In aging, these proteins are depleted leaving brain cells vulnerable to damage. Prevagen is made by Quincy Bioscience and was developed by scientists and University researchers in Madison, Wisconsin.

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# **Protein Chemistry**

Apoaequorin is capable of crossing the blood brain barrier (BBB) and the GI barrier

When cerebrospinal fluid (CSF) and blood plasma samples were taken from a population of dogs to which apoaequorin was orally administered, these samples showed quantifiable evidence that the supplement was present in the nervous and circulatory systems of the animals. Using a specially designed enzyme-linked immunosorbent assay (ELISA) linked to an electrochemiluminescent assay, it was also demonstrated that apoaequorin levels in dog CSF and plasma increased proportionately as a function of time. These data indicate that apoaequorin is capable of crossing the blood brain barrier and the gastrointestinal barrier via its presence in dog CSF and blood plasma, respectively.

# As we age, we lose about 85,000 brain cells each day.

Aging and how Prevagen® can help

In the United States, 10,000 baby boomers turn 50 every day. And although a touch of gray hair can look distinguished, there are other age-related issues that may be unwanted, such as the mild memory problems associated with aging. Your brain is made up of many small cells, and controls everything you do. To stay healthy your brain contains proteins that support brain health.

As we age, the body's ability to naturally produce this protein slows down. When this happens you may start to experience difficulty with memory, focus and concentration. Prevagen helps support brain cells by supplementing the proteins with the patented ingredient apoaequorin and supports healthier brain function.\* Researchers have discovered a protein that actually supports healthy brain function\*

For many years, researchers have known that the human brain loses cells throughout our lives, part of the natural process of aging. In fact, we lose about 85,000 brain cells per day, that is one per second, over 31 million brain cells every year! This impacts every aspect of your life... how you think and how you feel. Recently, scientists made a significant breakthrough in brain health with the discovery that apoaequorin can support healthy brain function, help you have a sharper mind and think clearer.\*

Prevagen Supports:

## **Healthy Brain Function\***

Apoaequorin is in the same family of proteins as those found in humans, but it was originally discovered in one of nature's simplest organisms—the jellyfish.

## Sharper Mind\*

Now produced in a scientific process, researchers formulated this vital protein into a product called Prevagen<sup>®</sup>. Prevagen is clinically shown to help with mild memory problems associated with aging.

## **Better Memory\***

This type of protein is vital and found naturally in the human brain and nervous system. As we age we can't make enough of them to keep up with the brain's demands. Prevagen supplements these proteins during the natural process of aging to keep your brain healthy. Prevagen comes in an easy to swallow capsule. It has no significant side effects and will not interact with your current medication.

## **Clearer Thinking\***

Just how well does Prevagen work? In a computer assessed, double-blinded, placebo controlled study, Prevagen improved memory for most subjects within 90 days.\*

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# Quincy Bioscience is a research-based biotechnology company

Prevagen® is the company's flagship consumer brand containing apoaequorin which has shown in published studies to be safe and effective. A landmark double-blind and placebo controlled trial demonstrated Prevagen improved short-term memory, learning, and delayed recall over 90 days.

As a result of the supplement's safety and effectiveness, Prevagen is now the number one selling brain support supplement in chain pharmacies across America according to Nielsen data (December 2014).

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# Nobel prize in chemistry

Apoaequorin (Pronounced: ā-poe-ē-kwôr-ĭn) was first discovered in 1962 in glowing jellyfish. Turns out these proteins caused the jellyfish to glow when the proteins bound to calcium ions. We've learned a lot about how calcium functions in the body by using apoaequorin. The Princeton professor who discovered this protein and his colleagues who helped develop the research won the Nobel prize in 2008. Prevagen does not cause any glowing!

## Quincy Bioscience and Apoaequorin

Founded in June of 2004 and based in Madison, Wisconsin, Quincy Bioscience is a biotechnology company focused on the discovery, development, and commercialization of novel technologies to address cognitive issues and other age-related health challenges. The core technology of the company is the innovative application of the calcium-binding protein Apoaequorin. Using this cutting edge protein originally discovered in jellyfish in the early 1960s, the company focuses on alleviating the consequences of impaired calcium homeostasis (the imbalance of calcium ions) which can lead to mild memory loss associated with aging.

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# **Frequently Asked Questions about Prevagen**

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## What is Prevagen?

Prevagen (Pronounced: prev-uh-gen) is a new brain health supplement and functions unlike other brain or memory supplements.\* Prevagen's patented ingredient is a new use for a well-known protein called "apoaequorin" which was originally found in a certain species of jelly fish.

Prevagen has been clinically tested and shown to improve mild memory problems that occur in aging.\*

## What are the most commonly reported benefits of Prevagen?

- Improves absentmindedness\*
- Improves memory\*
- Helps with mild memory problems associated with aging\*

## How long will it take to feel results?

Daily use for 30-90 days is a reasonable length of time to experience results.

## Do you have research supporting Prevagen?

Yes. A recent memory study showed Prevagen significantly supported cognitive function compared to placebo.

View the study [links to the Madison Memory Study]

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## What are all the asterisks (\*) for?

The asterisk (\*) denotes the FDA disclaimer for dietary supplements. This statement or "disclaimer" is required by law (DSHEA) when a manufacturer makes a structure/function claim on a dietary supplement label. In general, these claims describe the role of a nutrient or dietary ingredient intended to affect the structure or function of the body. The manufacturer is responsible for ensuring the accuracy and truthfulness of these claims; they are not approved by FDA. For this reason, the law says that if a dietary supplement label includes such a claim, it must state in a "disclaimer" that FDA has not evaluated this claim. The disclaimer must also state that this product is not intended to "diagnose, treat, cure or prevent any disease," because only a drug can legally make such a claim. For more information on dietary supplements, please visit www.fda.gov

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# Watch Prevagen Reviews

After over 15 years of research, we know Prevagen works to improve memory. But you don't have to take our word for it. On the following pages, you'll find Prevagen reviews from actual Prevagen users and hear how this brain health supplement, originally derived from a jellyfish, has helped them.

If you feel like you can relate to any of these people—whether you have trouble remembering names, or forget where you placed your keys—you may be experiencing age-related memory loss. This is a totally normal part of aging, but as you will see from watching these Prevagen reviews, you CAN take action to preserve your memories.

**The personal experiences you'll find here are from actual Prevagen users.** They are not from employees, friends or any party where compensation was offered as an inducement for providing a favorable testimonial. These are real reviews from real people.

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Mary remembers names better

I would say I probably noticed a difference within a month of taking Prevagen. That I was able to remember things better. And I wasn't as frustrated with myself, which was great.

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Jim improved his memory\*

I had such a positive experience from Prevagen that I would urge anybody to at least try it and see if it'll work for them, because it sure helped me.

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"Why not try it?"

It was about 3 weeks when the product began to work for me, and it's just getting better. I think its important to optimally age, there's no such thing as anti-aging, we're all going to age. But for me, this has been optimal.

# D. The Brain Health Guide, Mark Underwood, February 11, 2016 (Exhibit D)

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## CHAPTER 1 America's State of Brain Health

As we age, mild memory problems result in more difficulty in remembering. They also lead to an inability to focus, pay attention or stay on task. With advancing age comes increasing stress that can affect the brain.

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## CHAPTER 10 What is Prevagen?

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In order to stay healthy, the brain has specific proteins which help support brain cell function. Like other physiological processes in normal aging, the brain's level of these proteins decreases as we grow older. In the progression of normal aging, signs of forgetfulness become more obvious in our 50s. What was once easy to recall, now takes a little longer to retrieve.

# How often do these occur? You may want to ask a loved one to help you answer the questions!

- 1. Forget words you want to use in a conversation.
- 2. Set items down and then forget where you placed them.
  - 3. Repeat tasks that you already completed previously.
- 4. Forget details of what you did or what happened to you yesterday.
- 5. Ask someone the same question twice or telling [sic] the same story.

### Prevagen may help you improve your memory.\*

### **Breakthrough Brain Health Supplement\***

Prevagen is a safe and effective brain health supplement shown to improve memory.\* Prevagen supports brain function by using the protein apoaequorin to supplement the proteins that are diminished as we age.\* Supplementing with Prevagen has also shown to support the performance of the brain as demonstrated in cognitive testing. (More on this topic in the next chapter.)\*

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## **Chapter 11** THE LATEST SCIENCE

## PREVAGEN IMPROVES MEMORY\*

In 2010, Quincy Bioscience set out to build on the strong evidence that had been gathered on ability [sic] of apoaequorin to improve memory\*

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The goal of the Madison Memory Study was to measure Prevagen's ability to improve brain function using computer software in people experiencing normal age-related mild memory difficulties.\*

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A total of 218 adults ages 40 to 91 years old, were tested at predetermined onemonth time intervals and changes on specific assessments of cognitive function were measured at various time points during the study. The final results of the study were very encouraging. The data showed that people taking Prevagen had statistically significant improvement in several areas of memory compared to baseline and to placebo.\* The Prevagen group improved their scores in executive function, learning, memory, and word recall.\*

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### A Life of Quality

Have you ever heard something, and it made an impression on you? That is verbal learning. The act of remembering is primal. And the ability to summon information previously heard or seen is at our core. Being able to recall (and repeat) something that occurred earlier gives our lives greater meaning and purpose.

An example might be experiencing something someone said -- words from a colleague or an actor in a film. Those words -- anything from something profound and memorable to a joke, made an impression. You wanted to remember what you had just heard so you could relate it to others. Still another example might be hearing of a new book, and wanting to recall its title so you could later find out more. Both exhibit verbal learning, an essential brain activity that helps us retain information.

When the International Shopping Recall List Test was presented in the Madison Memory Study, a short shopping list was read aloud to subjects three times in succession with the participants given the chance to repeat what they could remember from the list after each time. Then the other tests were taken. When completed, testers asked each subject to recall verbally what was on the shopping list. The results were significant. Over the 90-day run of the study, subjects within a normal cognitive range and those with mild to moderate impairment fared well. Both groups had taken Prevagen during the three-month study period.

While little in this world is perfect, research, executed properly, uncovers ways that can improve the quality of our lives as we age. And being able to remember and repeat something verbally to others is an example of that quality. In the Madison Memory Study, the Prevagen arm significantly improved all of the above mentioned areas. For more about the study, see the appendix.

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## **EPILOGUE Researchers Discover "A Gift From The Sea"**

Mark Underwood, President and Co-Founder Quincy Bioscience

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Together with Mike Beaman, my business partner, we have developed a way for this unique jellyfish technology to be used for supporting the brain.\*

My goal is to help as many people as we can through the further development of Prevagen, by educating people on brain health, and by providing the public with a supplement that has been shown to work and is safe and scientifically sound.

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E. The Better Memory Show Infomercial (Exhibits E-1 (transcript) and E-2 (video))

ON SCREEN: Teri Barr

Television Investigative Journalist

TERI BARR: Hello, I'm Teri Barr. I've been a writer and television investigative journalist for more than 20 years, reporting on stories that can dramatically impact your health and well-being and the health of the people in your life you love and care about. Now, several years ago, I came across a story about a company doing some research on the brain, and I wanted to share this with you. They discovered a protein in jellyfish and they thought it might have the ability to support your brain and improve your memory. So, our special guest today is going to share with us exactly how this gift from the sea holds the key to improving normal age-related memory problems and so much more. I'm happy to have with us today Mark Underwood. He is a neuroscientist. He is also an author and has been featured in media all across the country talking about this discovery. And he also has a very special personal story to share. Mark, thank you for joining us today.

### ON SCREEN: Mark Underwood

President of Quincy Bioscience, Neuroscientist,

Author

MARK UNDERWOOD: Well, thank you, Teri. Memory problems are a big issue.

TERI BARR: Right.

MARK UNDERWOOD: As the baby boomers continue to age, we see more and more people that are struggling with day-to-day activities. They might become forgetful and lose their car keys or their cell phone, but certainly, you know, even some of us, well, we might walk into a room and forget where we're going.

TERI BARR: Mm-hmm.

MARK UNDERWOOD: -- or we're rummaging through the refrigerator and we forget what we're up to. Our research has shed some new light on how to improve these mild memory issues and, hopefully, it will be helpful for all those that are out there watching us today to learn more about how the brain works, how it changes with the aging process and, specifically, how we can use that unique protein found in the jellyfish to help our brains, well, get a little better, help our memory improve, and that's offering a lot of hope to people, those that have already been using Prevagen for some time, to help them with their day-to-day lives and make it a little bit easier.

MARK UNDERWOOD: A large double blind, placebo-controlled trial that we completed that showed great efficacy for Prevagen, showing statistically significant improvements in word recall, in executive function, and also in short term memory.

ON SCREEN: Word Recall

**Executive Function** 

Short-term Memory

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ON SCREEN: In a clinical trial participants showed improvement in memory in

90 days. Results published in peer reviewed journal in July 2011.

MARK UNDERWOOD: In the clinical trial, we were showing those benefits after the first month and those continued to improve after the second and third months.

•••

ON SCREEN: Sue H.

Prevagen User

SUE H.: When I first heard about Prevagen from my neighbor, Jan, I hoped that it would help my middle-aged memory become a little clearer. At work, I multitask all day long and I would find myself standing over somewhere wondering, why did I come back here. I find that a lot less now. Since I started taking Prevagen, I feel like I'm able to stay on task without wavering off and doing three different things, multitasking. I can stay on task and finish my project and it's just easier. We see probably 60 patients in our office a day. The doctor asked several of us if we remembered this certain patient and I was the only one that could come up with her name. They think I'm amazing. They just are amazed at my memory at work. I would tell my friends and relatives that Prevagen is great. I'd recommend it to all of them no matter what age just because of the benefits that I have seen in my focus and memory.

F. Prevagen Express Bus, Instagram Post Captured on March 31, 2016 (Exhibit F)



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28. To substantiate their claims that Prevagen improves memory, is clinically shown to improve memory within 90 days, is clinically shown to improve memory within 90 days, reduces memory problems associated with aging, is clinically shown to reduce memory problems associated with aging, provides other cognitive benefits, and is clinically shown to provide other cognitive benefits, Defendants primarily rely on one double-blind, placebo-controlled human clinical study using objective outcome measures of cognitive function. This study, called the Madison Memory Study, involved 218 subjects taking either 10 milligrams of Prevagen or a placebo. The subjects were assessed on nine computerized cognitive tasks, designed to assess a variety of cognitive skills, including memory and learning, at various intervals over a period of ninety days. The Madison Memory Study failed to show a statistically significant improvement in the treatment group over the placebo group on any of the nine computerized cognitive tasks.

29. After failing to find a treatment effect for the sample as a whole, the researchers conducted more than 30 post hoc analyses of the results, looking at data broken down by several variations of smaller subgroups for each of the nine computerized cognitive tasks. This methodology greatly increases the probability that some statistically significant differences would occur by chance alone. Even so, the vast majority of these post hoc comparisons failed to show statistical significance between the treatment and placebo groups. Given the sheer number of comparisons run and the fact that they were post hoc, the few positive findings on isolated tasks for small subgroups of the study population do not provide reliable evidence of a treatment effect.

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30. Nevertheless, Defendants widely touted the Madison Memory Study in their advertising. For example, the chart below appeared in the product labels for the Prevagen Products and Defendants' TV ads and website, prevagen.com. It indicates that a "double-blinded, placebo controlled study" showed dramatic improvement in recall tasks when, in fact, the results for the specific task referenced in the chart showed no statistically significant improvement in subjects taking Prevagen compared to subjects taking a placebo. In addition, Defendants eliminated from the chart one of the four data points in the study – day 60. At day 60, the recall task scores of subjects taking Prevagen declined from day 30, and were slightly worse than the recall task scores of subjects in the placebo group.



31. Defendants' claims that their product improves memory and cognition rely on the theory that the product's dietary protein, apoaequorin, enters the human brain to supplement endogenous proteins that are lost during the natural process of aging. Defendants developed their product and created their marketing campaign based on this theory. Defendants, however, do not have studies showing that orally-administered apoaequorin can cross the human blood brain barrier and therefore do not have evidence that apoaequorin enters the human brain. To the

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contrary, Defendants' safety studies show that apoaequorin is rapidly digested in the stomach and broken down into amino acids and small peptides like any other dietary protein.

### VIOLATIONS OF THE FTC ACT

32. Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), prohibits "unfair or deceptive acts or practices in or affecting commerce."

33. Misrepresentations or deceptive omissions of material fact constitute deceptive acts or practices prohibited by Section 5(a) of the FTC Act.

34. Section 12 of the FTC Act, 15 U.S.C. § 52, prohibits the dissemination of any false advertisement in or affecting commerce for the purpose of inducing, or which is likely to induce, the purchase of food, drugs, devices, services, or cosmetics.

35. For the purposes of Section 12 of the FTC Act, 15 U.S.C. § 52, Prevagen is either a "food" or "drug" as defined in Section 15(b) and (c) of the FTC Act, 15 U.S.C. § 55(b), (c).

### **COUNT I**

### FALSE OR UNSUBSTANTIATED EFFICACY CLAIMS

### (By Plaintiff Federal Trade Commission)

36. Through the means described in Paragraphs 19 through 31, Defendants have

represented, directly or indirectly, expressly or by implication, that:

- A. Prevagen improves memory;
- B. Prevagen improves memory within 90 days;
- C. Prevagen reduces memory problems associated with aging; and
- D. Prevagen provides other cognitive benefits, including but not limited to,

healthy brain function, a sharper mind, and clearer thinking.

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37. The representations set forth in Paragraph 36 are false or misleading, or were not substantiated at the time the representations were made.

38. Therefore, the making of the representations as set forth in Paragraph 36 constitutes a deceptive act or practice and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

### **COUNT II**

## FALSE PROOF CLAIMS

### (By Plaintiff Federal Trade Commission)

39. Through the means described in Paragraphs 19 through 31, Defendants have represented, directly or indirectly, expressly or by implication, that:

A. Prevagen is clinically shown to improve memory;

B. Prevagen is clinically shown to improve memory in 90 days;

C. Prevagen is clinically shown to reduce memory problems associated with

aging; and

D. Prevagen is clinically shown to provide other cognitive benefits, including but not limited to, healthy brain function, a sharper mind, and clearer thinking.

40. The representations set forth in Paragraph 39 are false.

41. Therefore, the making of the representations as set forth in Paragraph 39 constitutes a deceptive act or practice and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

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## VIOLATIONS OF NEW YORK STATE LAW

### COUNT III

## **REPEATED FRAUDULENT OR ILLEGAL ACTS**

## (By Plaintiff NYAG)

42. As set forth in Paragraphs 19 through 31 above, which allegations are

incorporated as if set forth herein, Defendants have committed acts and practices that constitute repeated and persistent fraudulent and illegal conduct in violation of NY Exec. Law § 63(12), including misrepresenting, directly or indirectly, expressly or by implication, that:

- A. Prevagen improves memory;
- B. Prevagen is clinically shown to improve memory;
- C. Prevagen improves memory within 90 days;
- D. Prevagen is clinically shown to improve memory within 90 days;
- E. Prevagen reduces memory problems associated with aging;
- F. Prevagen is clinically shown to reduce memory problems associated with

aging;

G. Prevagen provides other cognitive benefits, including but not limited to healthy brain function, a sharper mind, and clearer thinking; and

H. Prevagen is clinically shown to provide other cognitive benefits, including but not limited to healthy brain function, a sharper mind, and clearer thinking.

43. The representations set forth in Paragraph 42 are false or misleading, or were not substantiated at the time the representations were made.

## COUNT IV

# **DECEPTIVE ACTS OR PRACTICES AND FALSE ADVERTISING**

## (By Plaintiff NYAG)

44. As set forth in Paragraphs 19 through 31 above, which allegations are incorporated as if set forth herein, Defendants have committed acts and practices that constitute repeated and persistent fraudulent and illegal conduct and false advertising in violation of NY GBL §§ 349 and 350, including misrepresenting, directly or indirectly, expressly or by implication, that:

- A. Prevagen improves memory;
- B. Prevagen is clinically shown to improve memory;
- C. Prevagen improves memory within 90 days;
- D. Prevagen is clinically shown to improve memory within 90 days;
- E. Prevagen reduces memory problems associated with aging;
- F. Prevagen is clinically shown to reduce memory problems associated with

aging;

G. Prevagen provides other cognitive benefits, including but not limited to healthy brain function, a sharper mind, and clearer thinking; and

H. Prevagen is clinically shown to provide other cognitive benefits, including but not limited to healthy brain function, a sharper mind, and clearer thinking.

45. The representations set forth in Paragraph 44 are false or misleading, or were not substantiated at the time the representations were made.

#### CONSUMER INJURY

46. Consumers have suffered and will continue to suffer substantial injury as a result of Defendants' violations of the FTC Act, NY Exec. Law § 63(12), and NY GBL §§ 349 and 350. In addition, Defendants have been unjustly enriched as a result of their unlawful acts or practices. Absent injunctive relief by this Court, Defendants are likely to continue to injure consumers, reap unjust enrichment, and harm the public interest.

### THIS COURT'S POWER TO GRANT RELIEF

47. Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), empowers this Court to grant injunctive and such other relief as the Court may deem appropriate to halt and redress violations of any provision of law enforced by the FTC. The Court, in the exercise of its equitable jurisdiction, may award ancillary relief, including rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten monies, to prevent and remedy any violation of any provision of law enforced by the FTC.

48. NY Exec. Law § 63(12) and NY GBL §§ 349 and 350 authorize this Court to issue appropriate orders granting equitable or other appropriate relief for Defendants' violations of NY Exec. Law § 63(12) and NY GBL §§ 349 and 350.

### PRAYER FOR RELIEF

Wherefore, Plaintiff FTC, pursuant to Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), and Plaintiff State of New York, pursuant to NY Exec. Law § 63(12) and NY GBL §§349 and 350, and as authorized by the Court's own equitable powers, request that the Court:

A. Enter a permanent injunction to prevent future violations of the FTC Act, the NY Exec. Law, and the NY GBL by Defendants;

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B. Award such relief as the Court finds necessary to redress injury to consumers resulting from Defendants' violations of the FTC Act, the NY Exec. Law, and the NY GBL, including, but not limited to, rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten monies;

C. Award civil penalties in an amount up to \$5,000 for each violation of NY GBL § 349 and 350, pursuant to NY GBL § 350-d; and

D. Award Plaintiffs the costs of bringing this action, as well as such other and additional relief as the Court may determine to be just and proper.

Respectfully submitted,

Dated: January 9, 2017

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