



September 17, 2015

VIA EMAIL AND OVERNIGHT MAIL

Jessica Rich, Director
Bureau of Consumer Protection
Federal Trade Commission
600 Pennsylvania Ave. N.W.
Washington, DC 20580
[REDACTED]

Re: Deceptive Marketing for Prevagen

Dear Ms. Rich:

More than 5 million Americans suffer from memory loss.¹ Quincy Bioscience LLC² (Quincy) promises that its synthetic protein pill, Prevagen, can fix this health issue – improving memory in just 90 days. The problem is that there is no competent and reliable scientific evidence to support such a health and treatment claim, which means that Quincy is deceiving millions of consumers with its false marketing campaign.

On September 8, 2015, Truth in Advertising, Inc. (TINA.org) contacted Quincy notifying it of TINA.org’s investigation and findings, and asking that the company remedy the deceptive marketing.³ TINA.org gave Quincy a week to make corrections before forwarding this issue to the attention of the Federal Trade Commission, but the company has not responded or made any noticeable changes to its campaign.

A. Prevagen

Prevagen is an over-the-counter supplement taken orally that contains one active ingredient: a synthetically-made protein based on apoaequorin, a protein from bioluminescent jellyfish.⁴ Prevagen is sold in major stores, including Rite Aid Pharmacy, Walgreens, The Vitamin Shoppe, CVS Pharmacy, and Duane Reade.⁵ Since it was placed on the market in 2007, over two million bottles have been sold.⁶ In fact, Quincy, which made \$19.3 million in revenue in 2013, claims that Prevagen is the “#1 Brain Health support supplement.”⁷

B. Deceptive Marketing Claims

Quincy advertises Prevagen through its websites,⁸ television commercials,⁹ social media,¹⁰ and product packaging,¹¹ among other mediums. In its marketing materials, Quincy asserts that Prevagen is clinically tested and shown to rapidly improve memory. On its website, Quincy states, among other things:

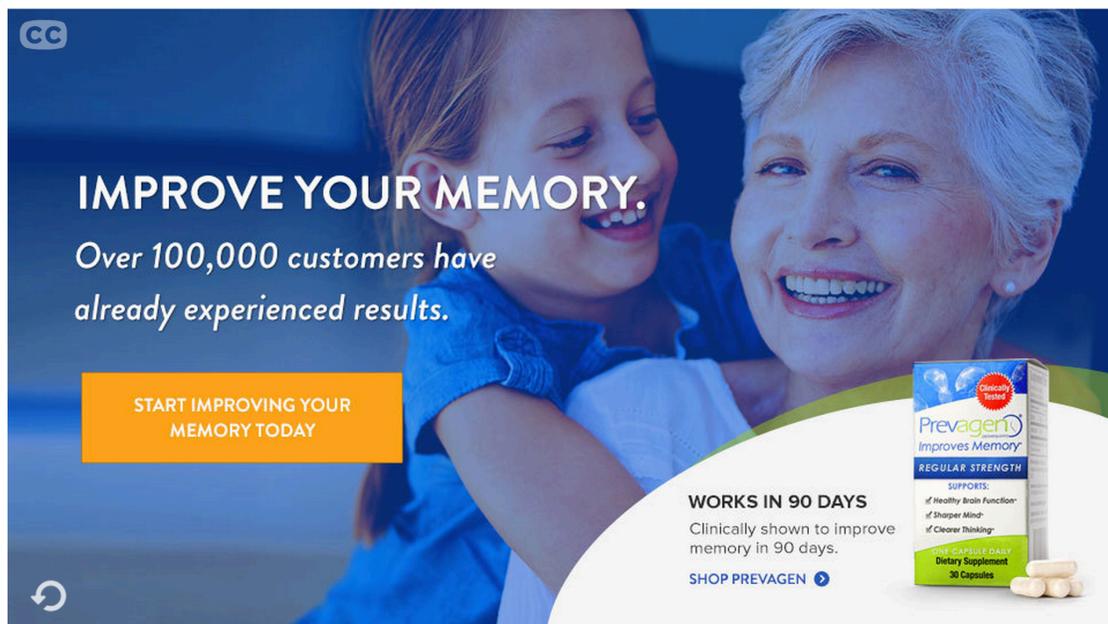
“Improve your memory. Over 100,000 customers have already experienced results.”¹²

“Clinically shown to improve memory in 90 days.”¹³

“Prevagen (Pronounced: prev-uh-gen) is a new brain health supplement made by Quincy Bioscience and functions unlike other brain or memory supplements.* The main ingredient is a patented protein called ‘apoeaquorin’ which was originally found in a certain species of jellyfish.”¹⁴

“Prevagen was tested in a large double-blind, placebo-controlled study using computers to assess brain performance. 218 adults over 40 year old participated in the three month study. Prevagen significantly improved learning and word recall.”¹⁵

“Only Prevagen contains the patented ingredient apoeaquorin, a unique protein originally obtained from a species of jellyfish called *Aequorea victoria* found in the Puget Sound. Apoeaquorin is a protein our brains need for healthy function but is diminished in the aging process.”¹⁶



The advertisement features a blue-tinted background image of a young girl with her arms around an elderly woman, both smiling. In the top left corner is a Creative Commons (CC) logo. The main headline reads "IMPROVE YOUR MEMORY." followed by the sub-headline "Over 100,000 customers have already experienced results." Below this is an orange button that says "START IMPROVING YOUR MEMORY TODAY". To the right, there is a box of "Prevagen Improves Memory REGULAR STRENGTH" capsules, with several capsules shown in front of it. Text next to the box states "WORKS IN 90 DAYS" and "Clinically shown to improve memory in 90 days." At the bottom right, there is a "SHOP PREVAGEN" link with a right-pointing arrow. A small circular refresh icon is in the bottom left corner.

Image featured on www.prevagen.com

The video featured on the Prevagen.com home page states, in part:

“Prevagen is a new experience for people that are looking for help with their memory [...] Did you know that we lose a brain cell every second? That’s over 86,000 a day, 31,000,000 brain cells every year. We need help to help our brains and protect our minds [...] The key to Prevagen is a unique protein called Apoeaquorin that was discovered in nature. It is a simple protein that was originally identified in a rare species of jellyfish over 50 years ago. This type of protein is important for the brain and the nervous system to do their jobs correctly. You make plenty of this protein when you are young but, in the aging process, your brain proteins level[s] decrease leading to common issues related to memory. Your brain needs this simple protein to help maintain the complex balancing act within your brain. When your brain is balanced it can take on the tasks that you need it to perform like thinking, remembering, and focusing. When your brain is balanced, you won’t feel as fatigued or foggy. With Prevagen, you will help maintain that balance and experience benefits that have already been demonstrated in clinical trials. Benefits for your short-term memory, word recall, and better decision-making. You can feel the difference that Prevagen makes. With Prevagen, you’ll have the assurances of safety and a history of scientific study and testing. Prevagen has been generally recognized as safe by the scientific community. Double-blinded and placebo controlled trials have demonstrated in healthy volunteers that cognitive benefits can be seen within weeks of starting Prevagen on a daily basis [...] And Prevagen is available in several strengths so that you can determine the performance of your brain [...]”

The Prevagen.com website also features a number of testimonials – some in text form and others in videos – that make similar treatment claims.¹⁷

In addition to the marketing on its websites, Quincy advertises Prevagen through television commercials, as well as infomercials.¹⁸ One commercial tells consumers:

“Can a protein originally found in a jellyfish improve your memory? Our scientists say ‘YES!’ Researchers have discovered a protein that actually supports healthier brain function. It’s the breakthrough in a supplement called Prevagen. As we age, we lose proteins that support our brain. Prevagen supplements these proteins and has been clinically shown to improve memory. It’s safe and effective for supportive healthier brain function, a sharper mind, and clearer thinking. Try Prevagen for yourself today.”¹⁹

The company makes similar claims on social media,²⁰ as well as on its product packaging, which states, among other things, “Clinically tested,” “Improves Memory,” “Supports: Healthy Brain Function, Sharper Mind, Clearer Thinking,” and “In a computer assessed, double-blinded, placebo controlled study, Prevagen® improved memory.”²¹

C. No Reliable Support for Prevacen's Memory Improvement Claims

To support these health and treatment claims, Quincy relies on three studies, two studies from 2009 and one from 2011, that it paid for and conducted on its own.²² However, despite the bold marketing claims that Quincy makes with regard to these studies, none support the proposition that Prevacen can improve one's memory. In order to adequately substantiate health and treatment claims, a study must be "conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results."²³ None of the three studies cited on Prevacen's website meets this standard.

Some of the deficiencies of these studies include:

- **Bias.** All three studies were conducted by Quincy, the very entity that controls the marketing of Prevacen and profits handsomely from its sale.
- **Publication.** None of the studies were published in peer-reviewed scientific journals. In fact, there is no study testing the effect of apoaequorin on memory in any peer-reviewed scientific literature.²⁴
- **Control.** Neither 2009 study was conducted with a control, which precludes one from drawing any conclusions about cause and effect.
- **Findings.** The 2011 study – the only one of the three that was double-blinded and placebo-controlled – exaggerates the significance of the findings by highlighting the change over time just within the participants who received the synthetic apoaequorin without comparison to the participants who received the placebo.²⁵ Such a comparison is scientifically meaningless. Further, the study did not find a significant difference between the two groups on cognitive function.
- **Sampling.** Both 2009 studies were based on a small group of participants' (56 and 55, respectively) self-reported responses to just three questions. In short, these two studies amount to nothing more than anecdotal information.
- **Relevance.** One of the 2009 studies – *Impact of Prevacen on Sleep Quality* – did not examine memory, but rather the supplement's impact on participants' amount of sleep, the amount of times they wake up at night, and the quality of their sleep. Thus, its findings are irrelevant to Quincy's claims regarding Prevacen's effect on memory.

Moreover, David S. Seres, MD, Associate Professor of Medicine and Director of Medical Nutrition at Columbia University Medical Center, an expert in nutrition and supplements, opined that Quincy's studies do not support the marketing claims it is making with regard to Prevacen. In addition to the defects articulated above, Dr. Seres relies on scientific principles of nutrition to further support his opinion. Specifically, the sole active ingredient

in Prevagen is a protein (synthetically-made apoaequorin).²⁶ As such, when ingested orally, it is denatured by the acid in the stomach, and broken down into smaller subcomponents in the intestine before uptake into the blood stream. For Prevagen to have any effect on the brain, it would have to survive digestion, be taken up in the bloodstream, and then pass through the blood-brain barrier, none of which is consistent with known biological or physiological facts.

In short, it is clear that Quincy wholly lacks any competent and reliable scientific studies to support its health and treatment claims regarding Prevagen.²⁷ Accordingly, the company's claims are deceptive and in violation of the FTC Act.

Conclusion

For the reasons stated in this letter, TINA.org urges the FTC to move quickly in order to halt Quincy's deceptive marketing of Prevagen.



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Cc: Michael Beaman, CEO, Quincy Bioscience
Mark Underwood, President, Quincy Bioscience

¹ One in Three People Over 70 Have Memory Impairment, Duke Medicine News and Communications, available at http://corporate.dukemedicine.org/news_and_publications/news_office/news/10261.

All sources are also saved on the enclosed flash drive.

² Quincy Bioscience LLC is a Wisconsin-based biotechnology company. <http://quincybioscience.com/about/company-history/>. The CEO of Quincy Bioscience is currently Michael Beaman, and the President is currently Mark Underwood. <http://quincybioscience.com/about/management-team/>.

The company is currently the subject of a class-action lawsuit filed against it in January 2015, which alleges, among other things, that Quincy Bioscience falsely and deceptively markets Prevacen as able to improve memory within 90 days. *See Racies v. Quincy Bioscience, LLC*, Case No. 3:15-cv-00292 (N.D. Cal.), Class Action Complaint, available at <https://www.truthinadvertising.org/wp-content/uploads/2015/03/Racies-v-Quincy-Bioscience-cmpt.pdf>. Another class-action lawsuit was filed against the company in 2014 making similar allegations but it has since been voluntarily dismissed by the plaintiffs. *See Guevera v. Quincy Bioscience, LLC*, Case No. 2:14-cv-04177 (C.D. Cal.), Notice of Voluntary Dismissal, dated Oct. 20, 2014, available at <https://www.truthinadvertising.org/wp-content/uploads/2015/09/Guevara-v-Quincy-BioScience-voluntary-dismissal.pdf>.

In addition, the FDA has investigated the company and sent it a warning letter in 2012 for, among other things, marketing Prevacen as a drug by claiming it can cure, mitigate, treat, or prevent disease, without FDA approval. *See* Warning Letter dated Oct. 16, 2012, available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm324557.htm>. At the time of the FDA's warning letter, Quincy Bioscience specifically referred to Alzheimer's Disease in some of its marketing materials, which it no longer does.

³ <https://www.truthinadvertising.org/wp-content/uploads/2015/09/Ltr-from-TINA-to-Quincy-Bioscience-re-Prevagen.pdf>.

⁴ <https://www.prevagen.com/about-improve-memory/>; <http://quincybioscience.com/products-prevagen/>; <https://www.prevagen.com/about-the-company/>. *See also* Safety assessment of the calcium-binding protein, apoaequorin, expressed by *Escherichia coli*, *Regulatory Toxicology and Pharmacology*, 69(2014) 243-249.

Prevagen comes in three strengths: Regular Strength, which contains 10mg of apoaequorin per dose, Extra Strength, which contains 20mg of apoaequorin per dose, and Professional Strength, which contains 40mg of apoaequorin per dose and is only available through healthcare providers. All three strengths come in capsule form and the Regular Strength comes in both a capsule and chewable table form. <http://quincybioscience.com/products-prevagen/>.

⁵ <https://www.prevagen.com/>.

⁶ <http://quincybioscience.com/quincy-bioscience-launches-prevagen-faq-video-series/>.

⁷ <https://www.prevagen.com/>; <http://quincybioscience.com/quincy-bioscience-launches-prevagen-faq-video-series/>; <http://www.inc.com/profile/quincy-bioscience>. *See also* <http://quincybioscience.com/about/management-team/>.

⁸ www.prevagen.com, www.prevagenes.com/, www.prevagenpro.com/, and www.quincybioscience.com/.

⁹ <https://www.prevagen.com/watch/>; <http://www.ispot.tv/ad/7lpj/prevagen-jellyfish-protein>.

¹⁰ <https://www.facebook.com/prevagen>; <https://twitter.com/prevagen>; <https://instagram.com/prevagen/>; <https://www.youtube.com/user/PrevagenSupplement>; <https://www.pinterest.com/prevagen/>; <https://plus.google.com/+prevagen/posts>; <http://prevagen.tumblr.com/>.

¹¹ See Images of Prevagen packaging, available at <https://www.truthinadvertising.org/wp-content/uploads/2015/09/Prevagen-packaging.pdf>.

¹² <https://www.prevagen.com/>. Similar claims are also made on www.prevagenes.com, www.prevagenpro.com, and www.quincybioscience.com/.

¹³ <https://www.prevagen.com/>

¹⁴ *Id.*

¹⁵ <https://www.prevagen.com/about-improve-memory/>

¹⁶ *Id.*

¹⁷ For example:

“After taking Prevagen, I started to notice that my ability to remember complex numbers was outstanding. The really amazing part is that I swear I was never able to remember them as well as I do now—not even when I was younger and had the best memory. I don’t intend to ever give up taking Prevagen.” – MIKKI

“I first learned about Prevagen through my sister who told me to check it out on the computer. My concentration, being able to focus and understand had improved....I have told other people about Prevagen who have memory problems. It works! I was at the point I could not remember what I was going to do from one room to another, now I am back to multi-tasking.” – MARY

“Boy, sure do love the stuff. Not only does it help my memory but has made me feel so great. It is so hard to explain. But my well-being is so different. This stuff is great! You know there are no words to describe the great feeling I have.” – PEGGY

“Prevagen has saved me. By 2 weeks, I was just starting to notice my recall was improving. Around 3-4 weeks, I noticed marked improvements, and was less confused much more focused. I believe it’s a wonderful product, I tell everyone I can about it.” – FRANK

“First things first ... thank you so much for Prevagen...my life is turning around. I might be too excited about getting some of my brain capacity back but, I'm going to cherish every

minute of my brain function as my life goes along (I'm 70), way too young to be sitting in a chair staring at the wall.” – MAXINE

“The day after starting Prevagen I was talking with my wife, Linda, and every time she could not think of the word or phrase she needed to express herself, it popped into my brain and I said it. I told her, ‘Prevagen Linda, start taking it.’” – BILL

“I am a 60 year old and thought I was losing my mind. I saw Prevagen and bought it. This stuff is stupid good, I can run circles around the young people at work now and feel sharp as a tack like I did 40 years ago. Well done guys!” – BRIAN

“...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...” MARY M.

“I don't think you really know always that you're forgetting things and we have a tendency to try to cover it. And now since I've been on Prevagen, I don't have that kind of problem with stuff anymore. In fact, everyone says to me, ‘How do you remember that stuff? Are you a private detective or something?’ It really does work good. It was about three weeks when the product began to work for me and it's just getting better [...] I think it's important to optimally age, and there's no such thing as anti-aging, we're all going to age, so for me, this has been optimum because I remember stuff other people don't. It's wonderful.” SUE B.

www.prevagen.com; www.prevagen.com/prevagen-reviews/watch/.

¹⁸ <https://www.prevagen.com/watch/>

¹⁹ <https://www.prevagen.com/watch/> (“Prevagen Supplements Brain Proteins” video); *see also* <http://www.ispot.tv/ad/7lpj/prevagen-jellyfish-protein>.

Two other commercials featured on the Prevagen website state:

“Prevagen is a step forward in promoting the health of your mental function. The brain contains vital proteins that support the work of each cell represented here in the color green. In the normal aging process, certain ions, shown in red, accumulate in the cell, which can lead to mild memory problems typically seen in aging. By taking Prevagen, you introduce into your cells a new protein that supports the health of each cell. Your brain is stronger and healthier. Your brain is now better equipped to fight the stresses of the aging process.” (Jellyfish Protein Improves Memory)

“[Woman]: Since I started taking Prevagen, I feel like I'm able to stay on task. [Man]: I had such a positive experience from it, that I would urge anybody to at least try it and see if it'll work for you because it sure helped me. [Woman 2]: Wow, this can really make you sharper, make your brain sharper and I thought, I'll give it a shot, and I did improve, I was shocked. [Voice-over]: Prevagen is clinically shown to improve memory. It's safe and effective for a sharper mind and clearer thinking. Try Prevagen for yourself today.” ([How to Protect Your Again Brain](#))

<https://www.prevagen.com/watch/>

²⁰ Prevagen’s Facebook page, for example, states “Prevagen® is clinically shown to improve memory and support healthy brain function.” <https://www.facebook.com/prevagen>.

²¹ See Images of Prevagen packaging, available at <https://www.truthinadvertising.org/wp-content/uploads/2015/09/Prevagen-packaging.pdf>.

²² The three studies cited by Quincy Bioscience as support for its health claims are: (1) *The Effects of the Calcium Binding Protein Apoaequorin on Memory and Cognitive Functioning in Older Adults*, Mark Y. Underwood, et al., 2011; (2) *Impact of Prevagen on Memory*, Prevagen Quality of Life Study, 2009; and (3) *Impact of Prevagen on Sleep Quality*, Prevagen Quality of Life Study, 2009. See <https://www.prevagen.com/research/>.

²³ <https://www.ftc.gov/tips-advice/business-center/guidance/dietary-supplements-advertising-guide-industry>; <https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf>.

²⁴ Quincy Bioscience falsely claims that one of its studies that examined the effects of apoaequorin on memory was published in a peer-reviewed journal in July 2011. See <https://www.prevagen.com/watch/>, “The Better Memory Show” at 5:31.

²⁵ In the 2011 study, participants who self-reported mild memory problems were randomly assigned to receive a 90-day supply of either apoaequorin or a placebo. See *The Effects of the Calcium Binding Protein Apoaequorin on Memory and Cognitive Functioning in Older Adults*, Mark Y. Underwood, et al., 2011, available at <https://www.prevagen.com/research/>. Participants underwent cognitive testing both at the outset of the study and again at the end, and then the results were compared to determine if there was any improvement over time. Rather than focus on any differences between the apoaequorin group and the placebo group, though, the study summary states:

“Overall, participants in the Apoaequorin arm saw a significant positive change over the three (3) month study period in[] Verbal Learning [,] Memory [,] Delayed recall [, and] Executive Function[.]”

Id. at 8. As stated above, this conclusion is scientifically meaningless without comparison to the participants who received the placebo. The study makes it clear that there was NOT a significant change over time between the apoaequorin participants and the placebo participants with regard to cognitive function. *Id.* at 4. In fact, the only area that appeared to show any significant difference between the two groups of participants – delayed recall – was based only on an unnumbered subset of participants (i.e., those who received a score of 0, 1, or 2 – out of a possible 8 – on the initial screening questionnaire). *Id.* (“There was a significant difference over time in the total number of errors reported on the [Groton Maze Recall] between the Apoaequorin arm and the Placebo arm for participants *who were considered within the range of normal to mild cognitive impairment (0 to 2) on the AD8* [screening tool].” (emphasis added). No mention is made about the other participants or even how many participants were in this subset.

Similarly, “[a] significant difference was seen over time between the Apoaequorin arm and the Placebo arm in the total number of errors made on the [Groton Maze Recall] *for participants who scored within the cognitive range 0 to 1 on the AD8* [screening tool].” *Id.* at 5. Again, there is no

mention of those who scored 2 or higher on the AD8. (The possible scores on the AD8 range from 0 to 8. *See* www.alz.org/documents_custom/ad8.pdf.)

In short, the study does not reveal all the data, which raises serious concerns with respect to the significance of the findings.

²⁶ *See* Safety assessment of the calcium-binding protein, apoaequorin, expressed by *Escherichia coli*, D. Moran, A. Tetteh, R. Goodman, and M. Underwood. *Regulatory Toxicology and Pharmacology*, 69(2014) 243-249.

²⁷ It is also interesting to note that the patent for PrevaGen indicates that it is for “[c]ompositions containing apoaequorin and methods for their use in treating symptoms and disorders related to calcium imbalances associated with, for example, sleep quality, energy quality, mood quality, memory quality or pain.” *See* United States Patent 8,796,213, available at <https://www.truthinadvertising.org/wp-content/uploads/2015/09/United-States-Patent-8796213.pdf> and <http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=%2Fnetacgi%2FPTO%2Fsrchnum.htm&r=1&f=G&l=50&s1=8796213.PN.&OS=PN/8796213&RS=PN/8796213>. According to this language, PrevaGen is intended to treat symptoms related to calcium imbalances – a rare condition that is only one of numerous potential causes of memory loss – yet none of the marketing materials for the product inform consumers of this fact. In addition, not one of the three studies cited by Quincy as support for its health claims mention whether any of the participants had calcium imbalances.