UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION and

THE PEOPLE OF THE STATE OF NEW YORK, by Eric T. Schneiderman, Attorney General of the State of New York,

Plaintiffs,

- against -

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.

17 Civ. 124 (LLS)

OPINION & ORDER

Plaintiffs Federal Trade Commission ("FTC") and the People of the State of New York, by Eric T. Schneiderman, Attorney General of the State of New York, seek injunctive and other equitable relief for alleged violations of federal and state deceptive advertising laws. All defendants move to dismiss the complaint for failure to state a claim upon which relief can

be granted. The two individual defendants, Mark Underwood and Michael Beaman, also move to dismiss for lack of personal jurisdiction.

BACKGROUND

Defendant Quincy Bioscience Holding Company, Inc. ("Quincy") is a Wisconsin based corporation. Compl. (Dkt. No. 1) ¶ 9. Defendants Quincy Bioscience, LLC, Prevagen, Inc., and Quincy Bioscience Manufacturing, LLC, also Wisconsin based companies, are wholly owned subsidiaries of Quincy. Id. ¶¶ 10-12. Quincy and its subsidiaries operated as a common enterprise in engaging in the conduct alleged in the complaint. Id. ¶ 17.

Underwood and Beaman are Quincy's co-founders and its two largest shareholders; Underwood owns 33% and Beaman owns 22% of its stock. Id. ¶¶ 13, 15. Underwood is Quincy's president and Beaman is its chief executive officer and former president. Id. Each is also a director of Quincy Bioscience, LLC, Prevagen, Inc., and Quincy Bioscience Manufacturing, LLC, and an officer of Quincy Bioscience, LLC and Prevagen, Inc. Id. The complaint alleges that "acting alone or in concert with others," Underwood and Beaman "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." Id. ¶¶ 14, 16.

Defendants manufacture and sell a dietary supplement known as Prevagen. Id. ¶ 21. Prevagen's active ingredient, apoaequorin (pronounced: ā-poe-ē-kwôr-ĭn), is a dietary protein originally derived from the jellyfish Aequorea victoria. Id. ¶ 19. Prevagen is sold in Regular Strength, Extra Strength, and Prevagen Professional, containing respectively 10, 20, or 40 milligrams of apoaequorin. Id. Prevagen is sold directly to consumers through defendants' websites, and indirectly through a host of pharmacies and retail establishments. Id. ¶ 21. Between 2007 and mid-2015, sales of Prevagen in the United States totaled $165 million. Id.

Defendants advertise Prevagen on their websites, through infomercials, short-form television commercials, social media, newspapers, and magazines. Id. ¶ 22. Their advertising includes representations that "Prevagen improves memory," that it "has been clinically shown to improve memory," that "A landmark double-blind and placebo controlled trial demonstrated Prevagen improved short-term memory, learning, and delayed recall over 90 days," that Prevagen "Helps with memory problems associated with aging," that "Prevagen is clinically shown to help with mild memory problems associated with aging," and that Prevagen can support "healthier brain function, a sharper mind and clearer thinking." Id. ¶ 27, Exs. A-F

Those representations rely primarily on the results of the Madison Memory Study. Id. ¶ 28. "The Madison Memory Study was a randomized, double-blind, placebo-controlled study designed to examine the effect of apoaequorin on cognitive function in older adults." Graham Decl. (Dkt. No. 35) Ex. 1 at 2; see Compl. ¶ 28. The study involved 218 adults between the ages of 40 and 91. Graham Decl. Ex. 1 at 4; see Compl. ¶ 28. "The primary objective of the Madison Memory Study was to determine whether Prevagen® with apoaequorin (10 mg) improves quantitative measures of cognitive function in community dwelling, older adults." Graham Decl. Ex. 1 at 1.

Because Prevagen is intended for healthy, non-demented individuals, its examiners used the AD8 screening tool[1] to differentiate between adults facing normal cognitive aging and those with early signs of dementia. Id. at 2. Participants were assigned AD8 scores of 0 through 8, with an AD8 score of 2 used to differentiate between those who are cognitively normal or very mildly impaired (with scores of 0-2) and those with higher levels of impairment (with scores of 3-8). Id. According to the examiners, "results from the AD8 0-1 and AD8 0-2 subgroups are the most relevant to the efficacy of the product." Id.

[1] "The AD8 is a brief, sensitive measure that reliably differentiates between nondemented and demented individuals." James E. Galvin, MD, MPH, et al., The AD8: a brief informant interview to detect dementia, 65 Neurology 559, 559 (American Academy of Neurology) Aug. 23, 2005, available at https://www.ncbi.nlm.nih.gov/pubmed/16116116 (last accessed Sept. 28, 2017).

Participants were divided into two groups: the experimental group received Prevagen, and the control group received a placebo. Id.; see Compl. ¶ 28. Both groups were instructed to take one capsule per day. Graham Decl. Ex. 1 at 2. At various intervals during the trial (days 0, 8, 30, 60, and 90), participants were assessed on a variety of cognitive skills using nine quantitative computerized cognitive tasks.[2] Id. at 2-4; see Compl. ¶ 28. No statistically significant results were observed for the study population as a whole on any of the cognitive tasks. Graham Decl. Ex. 1 at 5; Compl. ¶ 28. However, statistically significant results were observed between the experimental and control groups among the AD8 0-1 and AD8 0-2 subgroups. Graham Decl. Ex. 1 at 5-9; see Compl. ¶ 29. Participants in the AD8 0-1 subgroup who received Prevagen showed statistically significant improvements over those who received the placebo in three of the nine tasks (measuring memory, psychomotor function, and visual learning), and showed a trend toward significance in two more tasks (measuring verbal

[2] The nine cognitive measurement tests were, Graham Decl. Ex. 1 at 2, Table 1:

Tasks	**Cognitive Domain Measured**
International Shopping List (ISL)	Verbal Learning
International Shopping List - Delayed Recall (ISRL)	Memory
Groton Maze Learning (GML)	Executive Function
Groton Maze Learning - Delayed Recall (GMR)	Memory
Detection (DET)	Psychomotor Function
Identification (IDN)	Attention
One Card Learning (OCL)	Visual Learning
One Back (ONB)	Working Memory
Two Back (TWOB)	Working Memory

learning and executive function). Graham Decl. Ex. 1 at 6-9. Participants in the AD8 0-2 subgroup who received Prevagen showed statistically significant improvements over those who received the placebo in three of the nine tasks (measuring executive function, attention, and visual learning), and showed a trend toward significance in one more task (measuring memory). Id. Based on those findings, the study concluded that "Prevagen demonstrated the ability to improve aspects of cognitive function in older participants with either normal cognitive aging or very mild impairment, as determined by AD8 screening." Id. at 9.

Plaintiffs take issue with the study's conclusion. They allege that "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," and that post hoc subgroup analysis "greatly increases the probability that the statistically significant improvements shown are by chance alone." Compl. ¶ 29. They conclude that "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." Id.

Plaintiffs also allege that defendants' marketing campaign,

and their claims that Prevagen improves memory and cognition, rely on the theory that apoaequorin enters the human brain to supplement endogenous proteins that are lost during the natural process of aging. Id. ¶ 31. The complaint says that defendants have no studies showing that orally-administered apoaequorin can cross the human blood-brain barrier. Id. According to the complaint, studies conducted by defendants show that orally-administered apoaequorin is rapidly digested in the stomach and broken down into amino acids and small peptides like any other dietary protein. Id.[3]

Plaintiffs allege that the representations that Prevagen improves memory, improves memory within 90 days, reduces memory problems associated with aging, and provides other cognitive benefits, including but not limited to healthy brain function, a sharper mind, and cleared thinking, "are false or misleading, or were not substantiated at the time the representations were made," id. ¶¶ 36-37, and representations that Prevagen is clinically shown to improve memory, to do so within 90 days, to reduce memory problems associated with aging, and to provide other cognitive benefits, including but not limited to, healthy brain function, a sharper mind, and clearer thinking, "are

[3] This point, contradicted by canine studies whose relevance plaintiffs challenge, loses force when applied to the results of the subgroup study which make it clear that something caused a statistically significant difference between those subjects who took Prevagen and those given a placebo.

false," id. ¶¶ 39-40.

Plaintiffs claim that in making those representations defendants violate (1) 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," (2) section 12 of the FTC Act, 15 U.S.C. § 52, which prohibits false advertising of food or drugs, (3) section 63(12) of the New York Executive Law, which allows the Attorney General to apply for an order enjoining the continuance of repeated or persistent fraudulent or illegal acts, including misrepresentations, in the carrying on, conducting, or transaction of business, and directing restitution and damages, and (4) sections 349 and 350 of the New York General Business Law, which prohibit deceptive acts or practices and false advertising "in the conduct of any business, trade, or commerce or in the furnishing of any service in this state."

Defendants move to dismiss the complaint on the following grounds: (1) the complaint fails adequately to allege that the representations in the marketing materials violate sections 5(a) and 12 of the FTC Act; (2) the complaint fails to allege that the representations violate New York law; (3) the relief sought amounts to an unconstitutional restraint on commercial speech; (4) the action was commenced ultra vires as the FTC lacked a quorum to authorize it; (5) the court lacks personal jurisdiction over the individual defendants; and (6) the complaint fails

adequately to allege that the individual defendants personally participated in or had authority to control any unlawful conduct.

DISCUSSION

1. Failure to State a Claim upon Which Relief can be Granted

Legal Standard

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678, 129 S. Ct. 1937, 1949 (2009), quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570, 127 S. Ct. 1955, 1974 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id., citing Twombly, 550 U.S. at 556, 127 S. Ct. at 1965. "A pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" Id., quoting Twombly, 550 U.S. at 555, 127 S. Ct. at 1965. "Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" Id., quoting Twombly, 550 U.S. at 557, 127 S. Ct. at 1966 (brackets in Iqbal).

"The plausibility standard is not akin to a "probability requirement," but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts

that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of "entitlement to relief."'" Id., quoting Twombly, 550 U.S. at 556-57, 127 S. Ct. at 1965-66.

Alleging a Violation of the FTC Act

To establish liability under section 5(a) of the FTC Act, "the FTC must show three elements: '[1] a representation, omission, or practice, that [2] is likely to mislead consumers acting reasonably under the circumstances, and [3], the representation, omission, or practice is material.'" FTC v. LeadClick Media, LLC, 838 F.3d 158, 168 (2d Cir. 2016), quoting FTC v. Verity Int'l, Ltd., 443 F.3d 48, 63 (2d Cir. 2006).

Defendants do not challenge the complaint's sufficiency as to the first and third elements. With respect to the second element, however, they argue that aside from saying that the representations are false or unsubstantiated, the complaint does not allege facts from which it can be reasonably inferred that the representations at issue are false or unsubstantiated.

It is common ground that the Madison Memory Study followed normal well-accepted procedures, conducted a "gold standard" double blind, placebo controlled human clinical study using objective outcome measures of human cognitive function using 218 subjects, and that it failed to show a statistically significant improvement in the experimental group over the placebo group as

a whole. See, e.g., Compl. ¶ 28. That confined plaintiffs' attack to the studies of subgroups, and it is at that level that the complaint fails to do more than point to possible sources of error but cannot allege that any actual errors occurred. It points to the conduct of more than 30 post hoc[4] analyses of possible subgroups, most of whom showed no statistical significance between the treatment and placebo groups, but did show a statistically significant difference between the groups in the AD 0-1 and AD 0-2 subgroups whose members displayed improvement in memory after taking the supplement. That, of course, is the study relied upon by defendants. Here, plaintiffs' challenge never proceeds beyond the theoretical. They say that findings based on post hoc exploratory analyses have an increased risk of false positives, and increased probability of results altered by chance alone, but neither explain the nature of such risks nor show that they affected the subgroups performance in any way or registered any false positives. Nor do they give any reason to suspect that these risks are so large in the abstract that they prevent any use of the subgroup concept, which is widely used in the interpretation of data in the dietary supplement field. Thus, the complaint fails to show that reliance upon the subgroup data "is likely to

[4] This term seems to be used to imply some deficiency in integrity, never specified. It probably refers to no more than that the analytical work was done after the information-gathering process was completed.

mislead consumers acting reasonably under the circumstances," as is necessary to state its claim. FTC v. LeadClick Media, LLC, 838 F.3d at 168.

All that is shown by the complaint is that there are possibilities that the study's results do not support its conclusion. It does not explain how the number of post hoc comparisons run in this case makes the results as to the AD8 0-1 and AD8 0-2 subgroups unreliable, or that the statements touting the study's results are false or unsubstantiated. That "stops short of the line between possibility and plausibility of 'entitlement to relief.'" Iqbal, 556 U.S. at 678, 129 S. Ct. at 1949.

2. New York Law Claims

The federal law claims being dismissed, there is no satisfactory basis for the exercise of supplemental jurisdiction over the state law claims, and I decline to do so. 28 U.S.C. § 1367(c)(3) (district court may decline supplemental jurisdiction if it "has dismissed all claims over which it has original jurisdiction"); Bridgeman Art Library, Ltd. v. Corel Corp., 25 F. Supp. 2d 421, 431 (S.D.N.Y. 1998) ("When, as here, the federal claim is dismissed early in the litigation process, 'the presumption to decline jurisdiction is strong.'"). The New York State courts may find merit in the remaining claims under New York statutes, which are best left to them.

3. Defendants' Remaining Arguments

All claims being dismissed, there is no need to consider the defendants' remaining arguments, or the Underwood and Beaman motion denying jurisdiction.

CONCLUSION

The motions to dismiss (Dkt. Nos. 33, 36) are granted as to the federal law claims, and plaintiffs' state law claims are dismissed without prejudice.

So ordered.

Dated: New York, New York
September 28, 2017

Louis L. Stanton

LOUIS L. STANTON
U.S.D.J.