No. 17-3745

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

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-Appellants,

v.

QUINCY BIOSCIENCE HOLDING COMPANY, INC., QUINCY BIOSCIENCE, LLC, a limited liability company, PREVAGEN, INC., a corporation, DBA 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.,
Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

Brief of Amici Curiae Truth in Advertising, Inc., AARP, AARP Foundation, Advertising Law Academics, and National Consumers League in Favor of Appellants and in Support of Reversal

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CORPORATE DISCLOSURE STATEMENT

Truth in Advertising, Inc.

Truth in Advertising, Inc. is a 501(c)(3) nonprofit organization. It has no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

AARP and AARP Foundation

The Internal Revenue Service has determined that AARP is organized and operated exclusively for the promotion of social welfare pursuant to Section 501(c)(4) of the Internal Revenue Code and is exempt from income tax. The Internal Revenue Service has determined that AARP Foundation is organized and operated exclusively for charitable purposes pursuant to Section 501(c)(3) of the Internal Revenue Code and is exempt from income tax. AARP and AARP Foundation are also organized and operated as nonprofit corporations under the District of Columbia Nonprofit Corporation Act.

Other legal entities related to AARP and AARP Foundation include AARP Services, Inc., and Legal Counsel for the Elderly. Neither AARP nor AARP Foundation has a parent corporation, nor has either issued shares or securities.

National Consumers League

National Consumers League is also a 501(c)(3) nonprofit organization. It has no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

INTERESTS OF AMICI CURIAE

Amici are non-profit organizations and law professors who work to prevent and combat deceptive advertising and the harm it causes consumers.[1] Each amicus has significant expertise with respect to false and deceptive marketing, and in particular the use of unsubstantiated health claims to advertise products—the central issue in this case. Amici's unique expertise in the area of unsubstantiated health claims and the impact this deceptive marketing tactic has on consumers will assist this Court in better understanding the allegations at issue in this case. Furthermore, the issues presented in this case are of central importance to amici's work and missions.

Truth in Advertising, Inc.

Truth in Advertising, Inc. (TINA.org) is a nonprofit, nonpartisan consumer advocacy organization whose mission is to combat the systemic and individual harms caused by deceptive marketing. At the center of TINA.org's efforts is its website, www.tina.org, which provides consumers information about common

[1] The Federal Trade Commission and the People of the State of New York consent to amici filing this brief, while Quincy Bioscience and its co-appellees have stated that they take no position on amici's request to file this brief.

Pursuant to Fed. R. App. P. 29(4)(E), counsel for amici affirm that no counsel for a party authored this brief in whole or in part, nor did any person or entity, other than amici or their counsel, make a monetary contribution to fund the preparation or submission of this brief.

deceptive advertising techniques and applicable consumer protection laws, and broadcasts alerts about specific marketing campaigns, such as nationally-advertised "Simply American" products manufactured abroad and razor blades that last "up to a month"—provided a man shaves only three days per week.

TINA.org participates as amicus curiae in numerous court cases that pertain to false and deceptive marketing, both at the district court level (typically at the settlement approval stage to alert courts to proposed settlements that are not "fair, reasonable, and adequate," Fed. R. Civ. P. 23(e)(2)), as well as the appellate level. *See, e.g., Quinn v. Walgreen Co.* No. 12-cv-8187 (S.D.N.Y.) (responding to TINA.org's concerns and objection of class member represented by AARP Foundation, parties renegotiated their settlement agreement to make injunctive relief broader and perpetual, rather than limited to 24 months); *Lerma v. Schiff Nutrition Int'l,* No. 3:11-CV-01056 (S.D. Cal.), Dkt. 120, 141 (prompted by TINA.org's and AARP's amici curiae brief, plaintiffs sought to withdraw (and ultimately renegotiated) settlement); *Torres v. S.G.E. Mgmt., L.L.C.,* 838 F.3d 629 (5th Cir. 2016) (en banc) (after granting Truth in Advertising's Motion for Leave to file amicus curiae briefs, both in support of appellees' petition for rehearing en banc and in support of affirmance, the Fifth Circuit affirmed certification of class action challenging multilevel marketing scheme as an illegal pyramid scheme pursuant to RICO) (*cert. denied S.G.E. Mgmt., L.L.C. v. Torres,* 138 S. Ct. 76

(Oct. 2, 2017); *Frank v. Poertner*, No. 15-765 (S. Ct.) Brief Amicus Curiae for Truth in Advertising, Inc. Supporting Petitioner, (Jan. 14, 2016) (*cert. denied* 136 S. Ct. 1453 (2016)).

With respect to the use of unsubstantiated health claims in marketing, TINA.org has pursued more than 70 companies using deceptive health claims, has more than 65 databases on its website collectively cataloguing thousands of unsubstantiated health claims made about products, has sent dozens of warning letters to companies, and has filed numerous complaints with federal and state regulators. *See, e.g.*, TINA.org's Prevagen Action, https://www.truthinadvertising .org/prevagen-summary-of-action/. As a result of TINA.org's efforts in this area, hundreds of unsubstantiated health claims have been removed from the internet, companies have revamped their product labeling and other marketing materials, state and federal agencies have fined companies millions of dollars, and industry trade associations are more closely monitoring member companies' marketing. TINA.org has also been invited to speak at numerous national conferences on the use of unsubstantiated health claims in marketing, including "The Evolving Phenomenon of Direct-to-Consumer Neuroscience" Conference in February 2018 hosted by The Banbury Center to help identify and address key regulatory and ethical issues related to the growth of brain health products sold directly to consumers.

AARP and AARP Foundation

AARP is the nation's largest nonprofit, nonpartisan organization dedicated to empowering Americans 50 and older to choose how they live as they age. With nearly 38 million members and offices in every state, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands, AARP works to strengthen communities and advocate for what matters most to families, with a focus on health security, financial stability, and personal fulfillment. AARP's charitable affiliate, AARP Foundation, works to ensure that low-income older adults have nutritious food, affordable housing, a steady income, and strong and sustaining bonds. AARP and AARP Foundation regularly file amici curiae briefs in federal and state appellate courts—including those mentioned above—in support of efforts to eliminate unsubstantiated health-benefit claims that target and defraud older people.

AARP is also a member of the Global Council on Brain Health (GCBH), an independent collaborative of scientists, health professionals, scholars, and policy experts from around the world working in areas of brain health related to human cognition. The GCBH focuses on brain health relating to peoples' ability to think and reason as they age, including aspects of memory, perception and judgment.

Advertising Law Academics

Law Professor Amici are academics with an interest in promoting truth in advertising, which protects consumers and promotes fair competition. Professor

Rebecca Tushnet from Harvard Law School specializes in advertising law and has coauthored a leading casebook on the subject. *See* Rebecca Tushnet and Eric Goldman, ADVERTISING & MARKETING LAW: CASES AND MATERIALS, Volume 1 (3d ed. 2016). Professor Tushnet is joined here by Jessica Litman, University of Michigan School of Law; Ted Mermin, Executive Director, Berkeley Law Center for Consumer Law and Social Justice; Tamara R. Piety, University of Tulsa College of Law; Zahr Said, University of Washington School of Law; Dee Pridgen, University of Wyoming College of Law; Jeff Sovern, St. John's University School of Law; Brian Wolfman, Georgetown University Law Center.

National Consumers League

Founded in 1899, the National Consumers League (NCL) is America's pioneering non-profit consumer advocacy organization. For nearly 120 years, NCL has worked to promote fairness and economic justice for consumers and workers in the United States and abroad. To this end, NCL appears regularly before legislatures, administrative agencies, and courts across the country, advocating for the enactment and vigorous enforcement of laws that effectively provide truthful and accurate information to consumers about the products and services they purchase and use. To ensure that consumers possess the information necessary to make smart decisions about their health, NCL supports and devotes resources to

ensure the full and accurate labeling and advertising of foods, drugs, and dietary supplements.

INTRODUCTION AND SUMMARY OF THE ARGUMENTS

According to plaintiffs' complaint, Prevagen does not improve memory as Quincy claims. In support of their assertion that Quincy is deceiving millions of aging Americans with its unqualified marketing claims, plaintiffs rely on the fact that the active ingredient in Prevagen (apoaequorin) is a protein that is rapidly digested in the stomach and broken down into amino acids and small peptides just like any other protein making it impossible for apoaequorin to cross the human blood brain barrier to supplement proteins in the brain as Quincy's marketing contends. Compl. ¶ 31.[2]

[2] Plaintiffs' complaint contains numerous examples of Quincy marketing its supplement as being able to cross the blood brain barrier. *See, e.g.*, Compl. ¶ 27.C. ("Apoaequorin is capable of crossing the blood brain barrier (BBB) and the GI barrier," "Prevagen helps support brain cells by supplementing the proteins with the patented ingredient apoaequorin and supporting healthier brain function," and "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.") To support its claims that apoaequorin can cross the human blood brain barrier, Quincy only offered canine studies, which do not constitute competent and reliable substantiation for human health claims, *POM Wonderful, LLC v. FTC*, 777 F.3d 478, 505 (D.C. Cir. 2015), but which were incorrectly accepted by the District Court. Sept. 28, 2017 Opinion and Order, ECF No. 45, at fn 3.

These factual allegations are further supported by Quincy's own scientific study, the Madison Memory Study, which failed to show a statistically significant improvement in the treatment group over the placebo group. Compl. ¶ 28. This conclusion, however, would not assist in the marketing of Prevagen–marketing that has led to tens of millions of dollars in sales of Prevagen. *Id.* ¶ 21.

After completing the Madison Memory Study, Quincy's hired team of researchers went hunting through the data to see if they could find something to support Quincy's bold marketing message. To do so, the researchers conducted more than 30 *post hoc* analyses. In *post hoc* analysis, multiple comparisons are made after the experiment has been designed and the data collected. The more comparisons that are made, the more likely one is to find desired (but specious) results. This is why such aggressive use of *post hoc* analysis is known as data dredging or P-hacking. Using this technique, the researchers were able to find three out of nine tested tasks apparently showing a statistically significant improvement in two overlapping subgroups (the three tasks showing statistically significant improvement varied depending on how the subgroup was constituted) —a classic case of elevating likely false positives to the status of a proven claim. Armed with these unreliable and limited data, Quincy mounted a full-throttled marketing campaign with claims that "[a] landmark double-blind and placebo

controlled trial demonstrated Prevagen improved short-term memory, learning, and delayed recall over 90 days." Compl. ¶ 27.C.

Quincy's marketing never informs consumers of the severe limitations of its findings. Instead, Quincy's advertisements and marketing material convey unqualified efficacy and memory-enhancing establishment claims, unsupported by adequate substantiation. Quincy's selective touting of some *post hoc* analyses and nondisclosure of contrary findings from the Madison Memory Study in its marketing violates the law.

ARGUMENT

The District Court made its own appraisal of the factual allegations, picking and choosing for itself which facts to believe. The opinion plucks inaccurate factual assertions from Quincy's Motion to Dismiss (i.e., *post hoc* analysis "is widely used in the interpretation of data in the dietary supplement field"), inappropriately conflates a clinical study testing a product efficacy hypothesis with *post hoc* analyses, and rejects basic principles of statistics. Moreover, the District Court failed to match the alleged substantiation with the actual marketing campaign: Quincy is making the blanket pitch, "Prevagen improves memory," based upon subgroup data that, even if true, would support only a much more limited claim at best. This lack of qualification is itself misleading. The result is

that older Americans concerned about their cognitive condition are being misled to their detriment while Quincy continues to profit from its deceptively-induced sales.

I. *Post hoc* analyses are not study results upon which marketing claims can be based because they are likely to be specious.

The District Court stated:

> 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.

Sept. 28, 2017 Opinion and Order, ECF No. 45, at 10-11. This finding of fact should have lead the Court to the inevitable conclusion that Quincy cannot claim that its supplement improves memory. *See, e.g., POM Wonderful, LLC v. FTC,* 777 F.3d 478, 500 (D.C. Cir. 2015). But the opinion then takes a sharp left turn stating:

> 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** 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. (*fn: "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.")

Sept. 28, 2017 Opinion and Order, ECF No. 45, at 11.[3]

In direct contradiction to the Court's reasoning, *post hoc* analyses are not part of prospective, double-blind, clinical trials; they are separate retrospective analyses of trial data performed after the study has concluded to try to find patterns that were not primary objectives of the study. *See* Henry L. Elliott, *Post Hoc Analysis: Use and Dangers in Perspective*, 14(2) J. Hypertension S21 (1996). Thus, though important for generating hypotheses for future research, *post hoc* analyses are not definitive proof. *Id.* at S23 ("*Post hoc* analysis is of major importance in the generation of hypotheses. However, the hypothesis is created by the analysis and it has not been proved by any experiment…."). By ignoring the complaint's allegations about the most reliable evidence, the Court therefore failed to apply the correct legal standard.

[3] Out of over 30 *post hoc* analyses of smaller subgroups, Quincy chose to focus on two. The *post hoc* AD8 0-1 subgroup showed statistically significant improvements over those who received the placebo in three of nine tasks (measuring memory, psychomotor function, and visual learning). The overlapping *post hoc* AD8 0-2 subgroup showed statistically significant improvements over those who received the placebo in three of nine tasks (measuring executive function, attention, and visual learning), only one of which (visual learning) was the same as the AD8 0-1 group. The District Court identified a "trend toward significance" in two more tasks in AD8 0-1 (measuring verbal learning and executive function) and one in AD8 0-2 (measuring memory), but what that means is that those "trending" results were not statistically significant and thus a real effect was even less likely to have been shown by the study.

Though plaintiffs' complaint includes allegations that pertain to inadequate *post hoc* analyses, the critical allegations are those that demonstrate that the *best* evidence available—the overall study results—contradict Quincy's marketing claims. The allegations about Quincy's *post hoc* analyses simply show that those analyses are faulty and cannot override the actual study findings—which are that apoaequorin does not have a statistically significant impact on memory.

This is so because the results of a *post hoc* analysis are not reliable and "should be viewed with considerable skepticism." Elliott, *supra*, at S21. Once the study results are sliced and diced in multiple overlapping ways, the researchers have decreased their sample sizes and simultaneously increased the chances of getting a false positive. As researchers have stated:

> Even a seemingly simple research question (does drug A work better than drug B?) can lead to a surfeit of different analyses…In the vast number of routes, at least one will lead to a 'significant' finding simply by chance. Researchers who hunt hard enough will turn up a result that fits statistical criteria—but their discovery will probably be a false positive.

Michèle B. Nuijten, *Five Ways to Fix Statistics: Share Analysis Plans and Results*, Nature.com, Nov. 28, 2017; *see also* Peter Sleight, *Debate: Subgroup Analyses in Clinical Trials: Fun to Look At, But Don't Believe Them!*, 1(1) Curr. Control Trials Cardiovasc. Med. 25, 26 (2000) ("The play of chance is even more likely to produce spurious results when we examine subgroups in a trial, because of the diminished power to detect real differences, the increase in the variance around the

mean estimate, and the increasing statistical likelihood of a false finding when many subgroups are examined."); Richard Peto, *Current Misconception 3: That Subgroup-Specific Trial Mortality Results Often Provide a Good Basis for Individualising Patient Care*, 104(7) Br J. Cancer 1057, 1057 (2011) ("[A]pparent differences between the proportional risk reductions in different subgroups of the patient in a trial (or even in a meta-analysis of many trials) are often surprisingly unreliable…The play of chance often produces qualitatively wrong answers in particular subgroups in trials (or in meta-analyses of trials) that could, if interpreted incautiously, lead to millions of people being treated inappropriately or untreated inappropriately.").

To illustrate the impact chance plays in *post hoc* analyses, researchers using *post hoc* subgrouping by zodiac sign were able to "conclude" that Geminis and Libras wouldn't benefit from the administration of aspirin after a heart attack:

> All of the patients had their date of birth entered as an important 'identifier'. We were therefore able to divide our population into 12 subgroups by astrological star sign. Even in a highly positive trial such as [this study], in which the overall statistical benefit for aspirin over placebo was extreme ($P<0.00001$), division into only 12 subgroups threw up two (Gemini and Libra) for which aspirin had a nonsignificantly adverse effect (9% ± 13%).
>
> Of course most physicians (but not all!) laughed when they were presented with these results. However, when presented with other less ridiculous subgroup analyses they are likely to believe the results, and forget the example from astrology…

Debate: Subgroup Analyses in Clinical Trials, supra at 26. *See also Current Misconception 3, supra* at 1057 ("It would be unwise to conclude from such a result that patients born under the astrological birth sign of Libra or Gemini should not be given aspirin if they have a heart attack. However, similar conclusions based on 'exploratory' data-derived subgroup analyses, which from a purely statistical viewpoint are no more reliable than these astrological subgroup analyses, are often reported and believed, with inappropriate effects on worldwide clinical practice.").

The District Court made the same mistake Quincy hopes consumers will make: the Court stated that "the results of the subgroup study…make it clear that something caused a statistically significant difference between those subjects who took Prevagen and those given a placebo" (Opinion and Order fn. 3), in the apparent belief that the "something" had to be apoaequorin, as opposed to chance. But this belief is flawed and ignores the role that statistically probable false positives play in *post hoc* analyses. One reason *post hoc* subgrouping is so dangerous is that, with a threshold for statistical significance set at 95% confidence ($P \leq 0.05$),[4] a false positive result in one out of every twenty subgroups is

[4] In other words, 95% confidence means that, statistically, the chance that positive results reflect a false positive is 5%. Even in the absence of *post hoc* subgrouping, then, a researcher would expect tests of more than 30 groups to produce more than one result apparently significant at the .05 level if the supplement didn't work at

predictable. With a large number of potential subgroups (not just the subjects with cognitive scores on the AD8 scale of 0 or 1, and the overlapping set of subjects with scores from 0 to 2, but also subjects with scores from 0 to 3, 1 to 2, etc.), motivated researchers can find some subgroups that produce a positive result without falsifying any data, even when the odds are overwhelming that the result was a false positive.[5] Researcher Richard Harris has explained exactly why this process of "p-hacking" is misleading:

> The idea is simply to look at your data six ways from Sunday until some correlation reaches the p-value of .05 or less …. Statistical tests that scientists use to differentiate true effects from random noise rest on an assumption that the scientist started with a hypothesis, designed an experiment to test that hypothesis, and is now measuring the results of that test. P-values and other statistical tools are set up explicitly for that kind of confirmatory test. But if a scientist fishes around and finds something provocative and unexpected in his or her data, ….it's just plain wrong to recast your results as a new hypothesis backed by evidence. The fancy statistics aren't simply inappropriate; they are misleading.

Richard Harris, RIGOR MORTIS: HOW SLOPPY SCIENCE CREATES WORTHLESS CURES, CRUSHES HOPE, AND WASTES BILLIONS 139-141 (Basic Books 2017); *See also* Joseph P. Simmons et al., *False-Positive Psychology: Undisclosed Flexibility*

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all. The numbers here are thus plausibly more consistent with the presence of false positives than they are with the presence of true positives.

[5] Given that the two different subgroups that showed positive results here didn't even show positive results on the *same* set of memory tasks, it's even less plausible that the results represent a real effect with a physical cause rather than pure chance.

in Data Collection and Analysis Allows Presenting Anything as Significant, 22 Psychol. Sci. 1359 (2011).[6]

In short, Quincy's unqualified marketing claims are not supported by any competent and reliable scientific evidence, as is clearly alleged in plaintiffs' complaint.

II. Qualified findings cannot support unqualified marketing claims.

Even if one assumes, contrary to plaintiffs' allegations, that *post hoc* analyses carry the same weight as study results and are thus reliable, the narrow "results"—i.e., that apoaequorin improved performance on a subset of memory tasks only in individuals with either minimal or no cognitive impairment—do not support the broad, unqualified marketing claims at issue.

To make a marketing claim about the efficacy of a dietary supplement, the marketer must substantiate that claim with competent and reliable scientific evidence. *See, e.g., POM Wonderful, LLC v. FTC*, 777 F.3d 478, 504-505 (D.C. Cir. 2015). And where marketers make health claims about their products, such as that Prevagen can improve memory, the law requires substantiation that would be

[6] Scientific journals recognize that p-hacking creates specious results. The Nature Journals adopted author guidelines in 2005 warning submitters of the problem and requiring them to "explain how they adjusted the alpha level to avoid an inflated Type I error rate, or … select statistical tests appropriate for multiple groups…" *Running the Numbers*, 8(2) Nature Neuroscience 123 (Feb. 2005), https://www.nature.com/articles/nn0205-123.pdf; Nature Journal Scientific Reports Submission Guidelines, n.d., https://www.nature.com/srep/publish/guidelines.

accepted by the scientific community, in the form of at least one randomized and controlled human clinical trial (RCT) demonstrating statistically significant results. *Id.*

Further, the substantiating RCT must use participants who are representative of the consumers for whom the product at issue is intended and to whom the product is being marketed. *See FTC v. Wellness Support Network, Inc.*, 2014 U.S. Dist. LEXIS 21449, at *52 (N.D. Cal. Feb. 19, 2014) ("[T]o support Defendants' claims, 'experts would require consistent results from well-designed and well conducted studies in representative human populations that directly assess the specific therapeutic effects at issue.'"); *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 938, 941 (N.D. Ill. Sept. 8, 2006) (an RCT must "include patients who fulfill criteria for the type of [medical condition] to be treated …[T]he narrow patient population … might not be applicable to the likely population of [] consumers [purchasing the product at issue]."); Reference Manual on Scientific Evidence (Third), David H. Kaye and David A. Freedman, *Reference Guide on Statistics* 217 (2011) ("The population [of a study] is the whole class of units that are of interest; the sample is a set of units chosen for detailed study. Inferences from the part to the whole are justified only when the sample is representative.").[7]

[7] The District Court also incorrectly stated that "[i]t 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

In this case, Quincy's express, unqualified marketing claim is "Prevagen improves memory." Compl. ¶ 27 (other similar marketing claims include that Prevagen "has been clinically shown to improve memory"). Quincy's labeling and advertisements do not qualify or limit the population for whom this supplement is intended, even though the Madison Memory Study found no statistically significant results over the entire study population, and Quincy claims only to have showed—through *post hoc* analyses of subgroups—that Prevagen has some limited effect on certain tasks in adults who are "cognitively normal or very mildly impaired." Sept. 28, 2017 Opinion and Order, ECF No. 45, at 4 ("Prevagen is intended for healthy, non-demented individuals"). No one disputes that Prevagen has no effect on people with higher levels of impairment. *Id.*

Despite these data, the intended audience of Prevagen's marketing materials—older adults concerned about cognitive decline—are not made aware of these critical qualifications and are told only that Prevagen improves memory. But there can be no doubt that consumers with memory issues such as dementia and Alzheimer's are drawn to Prevagen by its false advertising claims. In fact,

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objective outcome measures of human cognitive function…" Sept. 28, 2017 Opinion and Order, ECF No. 45, at 10. In addition to the issues described above, an element of bias is present in the Madison Memory Study because it was conducted by Quincy, the very entity that markets Prevagen and profits handsomely from its sale. The study also was not published in a peer-reviewed scientific journal (and its evident flaws show that no peer review could have approved it). In fact, no study testing the effect of apoaequorin on memory has appeared in any peer-reviewed scientific literature.

Quincy's marketing assertions such as "you CAN take action to preserve your memories" seem targeted at consumers worried about or suffering from dementia and Alzheimer's. *See* Compl. at ¶ 27.C.

This kind of exaggeration and overgeneralization in the marketing claims for Prevagen cannot be substantiated by the Madison Memory Study or Quincy's *post hoc* analyses. *See, e.g., S.C. Johnson & Son, Inc. v. Clorox Co*., 241 F.3d 232 (2d Cir. 2001) (falsity found where comparative claims were presented as universal experiences when in fact the differences only appeared two-thirds of the time); *McNeil-PPC, Inc. v. Pfizer, Inc.*, 351 F. Supp. 2d 226 (S.D.N.Y. 2005) (falsity found where unqualified marketing claim directed at all consumers—i.e., "clinical studies prove that Listerine is as effective as floss against plaque and gingivitis" — was based on studies using qualified populations—i.e., only individuals with mild to moderate gingivitis; individuals with severe gingivitis or with any degree of periodontitis were excluded); *Garden Way Inc. v. The Home Depot Inc.*, 94 F. Supp. 2d 276 (N.D.N.Y. 2000) (falsity found where marketing claim was overinclusive and insufficiently specific compared to advertiser's actual testing); *Schick Manufacturing, Inc. v. Gillette Company*, 372 F. Supp. 2d 273 (D. Conn. 2005) (falsity found based on advertiser's exaggeration of product's physical effects); *see also Porter & Dietsch, Inc. v. FTC*, 605 F.2d 294 (7th Cir. 1979) (holding that scientific evidence showing that product at issue helps only some

people cannot be used as substantiation for the marketing claim that the product automatically helps all users); Federal Trade Comm'n, 16 CFR Part 255, Guides Concerning the Use of Endorsements and Testimonials in Advertising § 255.2 & n.1 (discussing FTC's findings that consumers perceive prominent claims as indicating typical results, even with disclaimers such as "results not typical").[8]

III. Enforcement of False Advertising Laws Is Essential to Stop Deceptive Marketing Practices that Capitalize on the Vulnerability of Older People.

The need to enforce the laws designed to protect consumers and, in this case, the more than five million older Americans suffering from memory loss from deceptive marketing claims cannot be overstated. *See One in Three People Over 70 Have Memory Impairment*, Duke Med. News and Commc'ns, Mar. 17, 2008, updated Jan. 20, 2016, https://corporate.dukehealth.org/news-listing/one-three-

[8] Quincy may argue that it made some qualifications in its marketing. However, attempts to qualify its memory improvement claim (e.g., stating on its website – but not on its product label or television commercials – that "Prevagen is clinically shown to help with mild memory problems associated with aging." Compl. ¶ 27.C.) are a far cry from clearly and conspicuously disclosing to its audience (i.e., older adults concerned about cognitive function) the important limitations of the product and the studies relied upon to make its claims. *See* Federal Trade Commission, Dietary Supplements: An Advertising Guide for Industry (Ap. 2001), available at https://www.ftc.gov/tips-advice/business-center/guidance/dietary-supplements-advertising-guide-industry (discussing effective disclosures); Leslie Fair, *What the Headline Giveth*, FEDERAL TRADE COMMISSION: BUSINESS BLOG . June 2, 2011, 2:36PM), https://www.ftc.gov/news-events/blogs/business-blog/2011/06/what-headline-giveth. But above all, the adequacy of Quincy's minor and occasional qualifications cannot be resolved on a motion to dismiss, given the plausible allegations of the complaint.

people-over-70-have-memory-impairment. Deceptive marketing of dietary supplements is an enormous problem that is growing opportunistically. "[M]arketing scams that prey disproportionately on seniors [for] unproven cures or treatments for various health conditions is a prime example of fraud impacting older Americans." Deceptive Marketing of Dietary Supplements: FTC Enforcement Activities, Before the Special Committee On Aging, 111th Cong. (May 26, 2010) (Prepared Statement of Federal Trade Commission, at 1). "Such marketing scams are particularly cruel by preying on consumers when they are most vulnerable and desperate, offering false hope and even luring them away from more effective treatments. For every serious disease, especially those with no proven cure, there are hundreds of marketers engaging in such fraud." *Id*. at 10.

A. Dietary supplement advertisers target older people.

Marketers have tuned into the fact that brain health, and particularly preventing memory loss and dementia, is a major concern for older people. *See* Laura Skufca, *2015 Survey on Brain Health*. Washington, DC: AARP Research, (Oct. 2015) https://doi.org/10.26419/res.00114.001 (finding nearly three quarters of survey participants over age 40 report that they are concerned about their brain health declining in the future). Thus, it comes as no surprise that, in 2015, the market for dietary supplements and products aimed specifically at brain health was valued at $2.3 billion, and is expected to increase by nearly 20 percent to reach

$11.6 billion by 2024. *Global Brain Health Supplements Market 2016-2024: Focus on Memory Enhancement, Mood and Depression, Attention and Focus, Longevity and Anti-aging, Sleep, Recovery and Dream Enhancement and Anxiety* (June 21, 2017, 06:38 AM EDT), https://www.businesswire.com/news/home/20170621005628/en/Global-Brain-Health-Supplements-Market-2016-2024-Focus.

Advertisers "are aggressively barraging information about [brain health] supplements, thus driving growth in consumer purchases." *Id.* Data gathered by the government's National Center for Health Statistics shows "that on a daily basis, 70 percent of older Americans use at least one supplement…. Twenty-nine percent of older Americans use four or more supplements each day." Patrick J. Kiger, *Older Americans Report High Use of Dietary Supplements: Many Take 4 or More Vitamins, Minerals, Herbs or Other Products Daily*, AARP, October 10, 2017, https://www.aarp.org/health/drugs-supplements/info-2017/dietary-vitamin-use-older-americans-fd.html?intcmp=AE-HEA-DRG-SUP-BB-ART.

B. <u>False health claims place older people at significant risk of harm.</u>

It has long been recognized that the integrity of dietary supplement information in the marketplace directly impacts people's health and safety. For example, some supplements interact in dangerous ways with prescription medication, which older adults often take for a variety of chronic health conditions. *See BRAIN HEALTH: Medications' Effects on Older Adults' Brain Function*,

https://www.nia.nih.gov/sites/default/files/d7/MedAgeBrain-Brochure.pdf (last visited Mar. 5, 2018).

Further, many people who use dietary supplements incorrectly assume that products being sold in the United States are regulated and have been tested for safety. They are not. The U.S. Food and Drug Administration (FDA) never evaluates marketing claims made to boost sales of dietary supplements. *See* FDA, Dietary Supplements: What You Need to Know, (updated 11/29/2017), https://www.fda.gov/Food/DietarySupplements/UsingDietarySupplements/ucm109760.htm (last visited Mar. 5, 2018).

"Even more troubling is the potential for harm caused by giving consumers false hope that nutritional products are the best solution to their health problems. … Such claims might lead consumers to forgo medically recommended therapies." *See* Diane Hoffman and Jack Scwartz, *Stopping Deceptive Health Claims: The Need for a Private Right of Action Under Federal Law*, 42 Am. J. Law & Med. 53, 56-57 (2016). "[C]laims that [ ] products actually can prevent, treat, or cure diseases . . . place consumers at great risk, putting their faith in unproven remedies in lieu of getting established therapies." *Advertising Trends and Consumer Protection*, Hearing Before Subcomm. on Cons. Prot., Product Safety and Insur., Comm. On Commerce, Science and Transp., 111th Cong. (July 22, 2009) (testimony of David Vladeck, Director, Bureau of Consumer Protection, Federal

Trade Commission). "Those who succeed in selling products based on fear or unsubstantiated claims that they will treat or cure serious diseases prey on the fear and desperation of the sick, the elderly, or those without the means to afford conventional medical care." *Id.* Fraudulent advertising such as that at issue in this case must be stopped.

CONCLUSION

If a federal district court was misled by Quincy's marketing and proffered substantiation, what hope is there for the millions of aging Americans concerned about memory loss and cognitive decline to accurately differentiate scientific facts from Quincy's fiction? This Court should reverse the District Court's September 28, 2017 Opinion and Order and remand the case for further proceedings.

DATED: March 6, 2018

Respectfully Submitted,

AMICI CURIAE IN FAVOR OF APPELLANTS AND IN SUPPORT OF REVERSAL

TRUTH IN ADVERTISING, INC., AARP, AARP FOUNDATION, ADVERTISING LAW ACADEMICS, and NATIONAL CONSUMERS LEAGUE

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Certificate of Service

I hereby certify that I electronically filed the foregoing Brief of Amici Curiae Truth in Advertising, Inc., AARP, AARP Foundation, Advertising Law Academics, and National Consumers League in Favor of Appellants and in Support of Reversal with the Clerk of the Court for the United States Court of Appeals for the Second Circuit by using the appellate CM/ECF system on March 6, 2018. All participants in the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

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